

Nuclear Material Events Database

Annual Report

Fiscal Year 2018

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ABSTRACT

This report presents information on trending and analysis of incidents/accidents (events) reported to the Nuclear Regulatory Commission (NRC) that involve radioactive material. The events are reported by NRC licensees, Agreement States, and non-licensees, and are recorded in the NRC's Nuclear Material Events Database. The reported events are classified into categories based on event reporting requirements defined in Title 10 of the Code of Federal Regulations. The categories in this report are (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, and (8) Other.

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ACRONYMS

ALARA as low as reasonably achievable

ALI annual limit on intake
AO abnormal occurrence

CEDE committed effective dose equivalent

CFR Code of Federal Regulations

CHHSA California Health and Human Services Agency

CT computed tomography
DDE deep dose equivalent

DE dose equivalent

DTRA Defense Threat Reduction Agency

EDE effective dose equivalent

EQP Equipment

EXP Radiation Overexposure

FBI Federal Bureau of Investigation

FY fiscal year

GTCC greater than class C

HDR high dose rate

HEPA high efficiency particulate air

HLW high-level waste

IAEA International Atomic Energy Agency

IEMA Illinois Emergency Management Agency

INL Idaho National Laboratory

LAS Lost/Abandoned/Stolen Material

LKS Leaking Sealed Source

LS least squares
MED Medical

MIBG metaiodobenzylguanidine

NA not applicable

NAD nuclear accident dosimeter

NMED Nuclear Material Events Database

NR not recovered

NRC Nuclear Regulatory Commission

OTH Other

PCM personnel contamination monitor

PET positron emission tomography

RAM radioactive material

REAC/TS Radiation Emergency Assistance Center/Training Site

RLM Release of Licensed Material or Contamination

RSO radiation safety officer

SAVI strut-adjusted volume implant

SDE shallow dose equivalent
SNM special nuclear material
SSE error sum of squares

SSR regression sum of squares

SST total sum of squares

TDSHS Texas Department of State Health Services

TEDE total effective dose equivalent

TRS Transportation

EXECUTIVE SUMMARY

The Nuclear Regulatory Commission's (NRC) Nuclear Material Events Database (NMED) contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The reported events are classified based on reporting requirements defined by Title 10 of the Code of Federal Regulations. The event reports are evaluated to identify statistically significant trends and events of higher significance (referred to as significant events in this report).

The significant events that occurred in Fiscal Year 2018 are summarized below. Some of these events are considered potential Abnormal Occurrences (AOs) until they complete NRC's formal AO determination process and are reported in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material Events

Six significant events occurred involving the loss of seven Category 1-3 sources as defined by the International Atomic Energy Agency's *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. Three Category 2 sources and four Category 3 sources were lost; all of which were recovered

Regarding the six significant events:

- None of the events involved Category 1 sources.
- Three of the events involved the loss of Category 2 sources (three total sources). These were all radiography sources contained within radiography exposure devices. One device fell from a truck en route to a jobsite, one device was left at a jobsite, and one device was in a truck that was stolen (a potential Abnormal Occurence). All of these sources were recovered.
- Three of the events involved the loss of Category 3 sources (four total sources). Two well logging sources were stolen from a storage facility, a brachytherapy source was lost during shipping, and a well logging source fell from a truck en route to a jobsite. All of these sources were recovered.

Medical Events

Eight significant events occurred, all of which were classified as potential Abnormal Occurrences:

- Four events involved high dose rate brachytherapy; three were doses delivered to unintended sites and one was a dose that was greater than prescribed.
- Two events involved Y-90 microsphere liver treatments where the dose was either delivered to an unintended site or greater than prescribed.
- One event involved prostate brachytherapy seeds implanted into an unintended site.
- One event involved a patient whose skin was radioactively contaminated during an administration of I-131 for brain cancer.

Radiation Overexposure Events

Three significant events occurred, all of which involved radiographers who received exposures from unshielded radiography sources.

Release of Licensed Material or Contamination Events

One significant event occurred. A patient known to be contaminated with F-18 during a PET scan was discharged without being decontaminated.

Leaking Sealed Source Events

No significant events occurred.

Equipment EventsNo significant events occurred.

Transportation EventsNo significant events occurred.

Other Events

No significant events occurred.

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1. INTRODUCTION

1.1 Overview and Objectives

Nuclear material event reports are evaluated to identify statistically significant trends and significant events. The reported information aids in understanding why the events occurred and in identifying any actions necessary to improve the effectiveness of the nuclear material regulatory program.

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by the Idaho National Laboratory (INL) and contains over 25,000 records of material events submitted to the NRC from January 1990 to present.

The events in this report are classified into the following categories based on event reporting requirements defined by Title 10 of the Code of Federal Regulations (CFR):

- Lost/Abandoned/Stolen Material (LAS),
- Medical (MED),
- Radiation Overexposure (EXP),
- Release of Licensed Material or Contamination (RLM),
- Leaking Sealed Source (LKS),
- Equipment (EQP),
- Transportation (TRS), and
- Other (OTH).

A description of categories addressed in this report and associated screening criteria are presented in Appendix A.

1.2 NMED Data

A single occurrence report may be captured in more than one NMED event category. For example, a report may describe a loss of licensed material that also resulted in a radiation overexposure. In such a case, both event categories are recorded in the NMED and identified by the same report number (referred to as an item number in the database).

The data presented in this report are limited to reportable events that occurred between October 1, 2008, and September 30, 2018. The data were downloaded from the NMED on November 30, 2018. Because the NMED is a dynamic database that is updated daily, variations in data may be encountered over time. Furthermore, even though many events were reported and entered in the database for operational experience purposes, only those events required to be reported by 10 CFR are addressed in this report.

This report displays annual trend data for each of the event categories for a 10-year period. A trend analysis was performed on each event category to identify the existence or absence of a statistically significant trend. If a statistically significant trend exists, the display indicates the direction and

approximate rate of change with a trend line. For the purposes of this report, a statistically significant trend exists if the analysis indicates that the computed fit and slope of a least squares linear model is valid at a 95% confidence level. A primer on the statistical methods employed in the trend analysis is presented in Appendix B.

Note that the trending methodology is not normalized; the trend only considers the number of reported events and does not directly account for external issues such as changes to regulatory requirements or changes in the number of licensees. For example, an increasing trend in the number of medical events could be caused by an increase in the number of medical procedures being performed. Likewise, an event type showing a decreasing trend for NRC licensees and an increasing trend for Agreement State licensees could be caused by States becoming Agreement States (resulting in fewer NRC licensees and more Agreement State licensees).

Reporting guidance for Agreement States is provided in the *Handbook on Nuclear Material Event Reporting in the Agreement States*. The handbook is an appendix to the NRC Office of Nuclear Material Safety and Safeguards procedure SA-300, *Reporting Material Events*. Access to NMED is available to the staff of NRC, Agreement State, and Federal agencies at http://nmed.inl.gov.

For assistance on searches or other questions, contact Robert Sun (nmednrc@nrc.gov, 301-415-3421).

2. ANALYSIS OF NMED DATA

Event reports submitted to the NRC involving nuclear material are reviewed, categorized, and entered into the NMED. Charts are provided to display trends in annual data for the most recent 10-year period (FY09-18).

2.1 All NMED Events

Figure 1 displays the annual number and trend of NMED events that occurred during the 10-year period. The trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line). However, the Total events and Agreement State-regulated events do not represent statistically significant trends (indicated by the absence of trend lines).

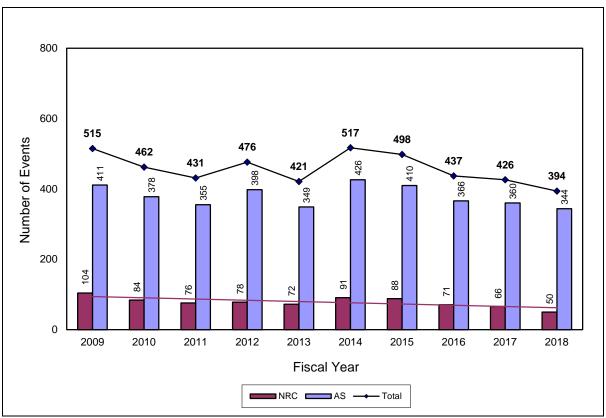


Figure 1. All NMED Events (4,577 total)

The following observations are made regarding the data in Figure 1.

- In FY18, 374 occurrences accounted for 394 events; a single occurrence can be classified in different event categories.
- The most recent year's data are typically many records less than their final value when subsequent updates and late reports are received (see Appendix D, Figure D-1).
- The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.

Table 1 displays a summary of the trending analysis for all NMED event types included in this report. A more detailed discussion of the trending analysis results can be found in the section of this report devoted to each event type.

Table 1. Summary of Trending Analysis

Event Type	Total	NRC	Agreement State
All NMED Events		*	-
Lost/Abandoned/Stolen Material (LAS)	1	•	-
Medical (MED)	1	•	-
Radiation Overexposure (EXP)		-	-
Release of Licensed Material or Contamination (RLM)	×	*	-
Leaking Sealed Source (LKS)	-	-	-
Equipment (EQP)	-	-	-
Transportation (TRS)	-	-	-
Other (OTH)	NA	NA	NA

Notes:

- Indicates a statistically significant increasing trend.
- indicates a statistically significant decreasing trend.
- • indicates no statically significant trend.
- NA indicates that the data does not support trending analysis.

2.2 Lost/Abandoned/Stolen Material

2.2.1 Ten-Year Data

Figure 2 displays the annual number and trend of LAS events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

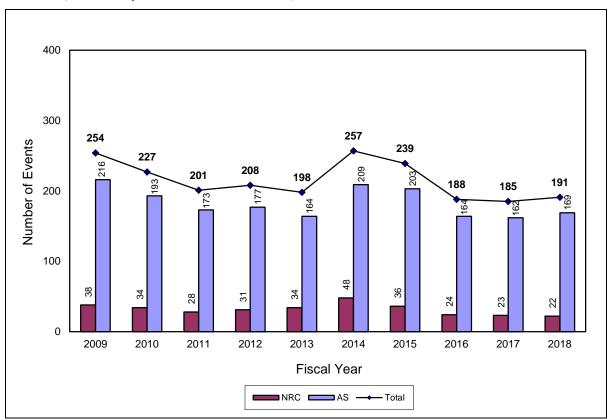


Figure 2. Lost/Abandoned/Stolen Material Events (2,148 total)

Appendix C contains a list of radionuclides derived from the International Atomic Energy Agency's (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. These radionuclides are grouped by the amount of radioactivity into five categories that correspond to the relative hazard, with Category 1 being the most hazardous.

For this report, IAEA Category 1 through 3 source events (excluding irretrievable well-logging source events) are considered significant. Regardless of IAEA category, events involving irretrievable well-logging sources are not considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 2 displays the number of sources lost (approximately 3,502, excluding irretrievable well-logging sources) during the 10-year period and the number that have not been recovered (approximately 1,812), grouped by IAEA category where possible. These included two Category 1 sources, 49 Category 2 sources, and 37 Category 3 sources; all of which were recovered, with the exception of two Category 2 and three Category 3 sources.

Table 2. Number of Sources Lost/Abandoned/Stolen (LAS) and Sources Not Recovered (NR) - Excluding

Irretrievable Well Logging Sources

	Fiscal Year											
Cate	gory	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
1	LAS ⁴	0	0	0	0	0	0	2	0	0	0	2
	NR ⁵	0	0	0	0	0	0	0	0	0	0	0
2	LAS	2	0	2	3	10	5	9	8	7	3	49
2	NR	0	0	1	0	0	0	0	0	1	0	2
2	LAS	1	4	4	7	3	4	4	5	1	4	37
3	NR	0	1	0	1	0	0	1	0	0	0	3
4	LAS	51	76	44	44	24	53	44	43	31	37	447
4	NR	25	26	23	14	8	26	20	19	9	17	187
_	LAS	76	89	82	83	70	88	81	82	50	57	758
5	NR	20	28	11	25	7	33	31	47	14	27	243
_	LAS	2	1	1	0	1	1	2	1	10	4	23
< 5	NR	2	1	0	0	0	0	2	1	1	4	11
Activity	LAS	5	13	12	9	7	3	3	1	3	1	57
Not Known ¹	NR	0	1	0	0	0	0	1	0	0	0	2
Nuclide	LAS	0	0	6	0	1	0	1	0	1	0	9
Not Known ²	NR	0	0	5	0	0	0	0	0	0	0	5
	LAS	270	100	200	102	171	220	100	223	151	100	2420
Other ³		279	183	209	193	174	330	192		154	183	2120
	NR	175	127	139	132	92	257	110	160	65	102	1359
	LAS	416	366	360	339	290	484	338	363	257	289	3502
Total	NR	222	184	179	172	107	316	165	227	90	150	1812

Notes:

- 1. The "Activity Not Known" category includes sources containing radionuclides listed in Appendix C for which the activity was not reported. Therefore, the sources were not included in Categories 1 through 5.
- 2. The "Nuclide Not Known" category includes those sources for which the radionuclide was not reported. Thus, the sources were not included in Categories 1 through 5 or Other.
- 3. The "Other" category includes sources containing radionuclides not included in Appendix C.
- 4. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).

5. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 through 3 "not recovered" source counts were corrected for the "partially recovered" source events.

Tables 3 and 4 provide more detail regarding the 10-year and current year "not-recovered" data highlighted in Table 2 in yellow and green, respectively. Table 3 displays radionuclide data pertaining to the IAEA Category 1 through 3 sources lost during the 10-year period that have not yet been recovered. The Decayed Activity values are conservative estimates in that the values are typically decayed from the loss date instead of the manufacturer's assay date. As a result, the actual decayed activities (based on the manufacturer's assay date) are likely less than the estimates. Table 4 is similar to Table 3, but limited to the current year.

Table 3. Summary of IAEA Category 1-3 Sources Not Recovered (FY09-18)

Radionuclide	Half-life ¹	Number of Sources Not Recovered ^{2,3}	Total Activity (Ci)	Total Decayed Activity (Ci) ⁴	Total Decayed Activity IAEA Category
Ir-192	73.83 days	3	67.0	0.0	4
Pu-238	87.7 years	2	5.3	5.1	3
Total		5	72.3	5.1	3

Notes:

- 1. Half-life values from the Chart of the Nuclides, 16th Edition.
- 2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).
- 3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the "partially recovered" source events.
- 4. The source activities were decayed from the event date to 11/30/2018 (data download date).

Table 4. Summary of IAEA Category 1-3 Sources Not Recovered (FY18)

Radionuclide	Half-life ¹	Number of Sources Not Recovered ^{2,3}	Total Activity (Ci)	Total Decayed Activity (Ci) ⁴	Total Decayed Activity IAEA Category
		0			
Total		0			

Notes:

- 1. Half-life values from the Chart of the Nuclides, 16th Edition.
- 2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).
- 3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the "partially recovered" source events.

4. The source activities were decayed from the event date to 11/30/2018 (data download date).

2.2.2 FY18 Data

One hundred ninety-one LAS events occurred in FY18, eight of which involved irretrievable well logging sources. Excluding the irretrievable well logging sources, approximately 289 sources were lost/abandoned/stolen, 150 of which have not been recovered. Of the 289 lost sources, none were Category 1, three were Category 2, and four were Category 3 sources; all of which were recovered.

Six of the FY18 LAS events were considered significant (involved Category 1-3 sources). Note that regardless of IAEA category, events involving irretrievable well logging sources are not considered significant.

Significant Events - Category 1 Source Events None

Significant Events - Category 2 Source Events

Item Number 180015 - A radiography services company reported the loss and recovery of a radiography exposure device that contained a 1,513.3 GBg (40.9 Ci) Ir-192 source. The corporate radiation safety officer (RSO) stated that radiographers had placed the exposure device on the tailgate of a truck at the company's facility on 12/29/2017. The radiographers left the facility and headed to a work site in Groves, Texas. In Nederland, Texas, the radiographers realized that they had not secured the device and pulled over. The device was not on the tailgate of the truck. The corporate RSO was contacted and at least two teams began searching for the lost device. The device did have both storage caps in place. The corporate RSO stated that the exposure rate on contact with the device was 0.17 mSv/hour (17 mrem/hour) with a transport index of 0.4. Local law enforcement was contacted and responded to the company's facility. Approximately 40 people searched for the device, including fire fighters, emergency response personnel, and company personnel. The exposure device was found on 12/29/2017, 6.9 miles from the company's facility. Pictures of the device show that the outer coating was scratched, but the device itself did not appear to be damaged. The company sent the exposure device to the manufacturer for inspection who determined that the device was in good working order. The involved radiographer's qualifications were suspended. The company provided additional training on source security to all of their radiographers.

Item Number 180238 - A radiography services company reported that a radiographic exposure device that contained a 3,182 GBq (86 Ci) Ir-192 source was left unattended at a job site on 5/18/2018. Due to a miscommunication, the device was left inside a refinery in Richmond, California, for several hours before it was discovered and placed back under the company's control. The California Health and Human Services Agency investigated the incident. The radiography trainer's employment was terminated. The radiography assistant was suspended for two days and given additional training. The company conducted safety stand-down meetings with all radiographers to discuss the incident, the violations, and ways to prevent recurrence. Additionally, the company revised production and safety processes and increased field audits by management personnel.

Item Number 180416 - A radiography services company reported the theft and recovery of a radiography exposure device that contained a 3,996 GBq (108 Ci) Ir-192 source. The company truck containing the device was stolen from a gas station in Ripley, West Virginia, on 9/1/2018. The company notified the West Virginia State Police and the vehicle was recovered. The company recovered and inspected the device; no damage was discovered. They stated there was no radiological impact to the public or employees. This event was classified as a potential Abnormal Occurrence.

Significant Events - Category 3 Source Events

Item Number 170490 - A well logging company reported the theft and recovery of two Am-Be well logging sources, each containing an activity of 111 GBq (3 Ci). The two sources were stolen from their storage area in Kern County, California, on 10/15/2017. Locks had been cut and the sources removed

from their 12-foot storage pipe. A 2,500 pound calibration water tank was also stolen. The FBI was notified of the event on 10/15/2017. The two well logging sources were recovered on 10/16/2017. It was determined that an unauthorized individual had accessed the sources and removed them from their storage location. The individual had discarded them a short distance away without any knowledge of what they were. The individual also took the water calibration tank for his personal use. The well logging sources were returned to the company. The California Health and Human Services Agency responded to the site on 10/16/2017. The company relocated their sources to a different property. A written agreement between the company and the property owner is in place. Their security system was repaired and reinstalled at the new storage location. All alarm notifications received by the company will be immediately investigated and not dismissed as a false alarm.

Item Number 180114 - A radioactive source vendor reported the loss of a 384.8 GBq (10.4 Ci) Ir-192 brachytherapy source. The common carrier had not delivered the source to the applicable hospital. The shipping date from the vendor was 2/26/2018. The common carrier communicated with the vendor on 3/9/2018 that they could not locate the source in their tracking system or in their Memphis, Tennessee, hub. The source was eventually delivered to the hospital on 3/23/2018.

Item Number 180417 - A well logging company reported the loss and recovery of a shipping container holding a 185 GBq (5 Ci) Am-Be source while en route to a temporary job site. The company stated that no radiation exposures occurred to the public. The crew left their facility on 7/12/2018 and traveled approximately 1.5 hours to a job site in Winnie, Texas. Upon arrival, the crew found that the shipping container had fallen out of the truck's storage compartment. The compartment had been locked, but the latch had worn enough to allow the door to come open and the container was not physically secured to the transport vehicle as required. The company searched and found the shipping container about 50 to 60 feet off the side of the road near the town of Winnie, Texas. The container was locked, undamaged, and with the source inside. To prevent recurrence, a D-ring was installed inside the transport compartment of company trucks to which shipping containers will be chained.

Events of Interest

Item Number 170485 - A university reported the loss of a nuclear accident dosimeter (NAD) that contained a 1 gram plutonium source, consisting primarily of 2.26 GBq (61 mCi) of Pu-239. An inventory discrepancy was identified on 10/5/2017. The university received 14 NADs on loan from the Department of Energy (through the Idaho National Laboratory) in 1991. On 2/18/2003, the university documented that this particular NAD was found to have detectable surface contamination levels of 11.32 and 10.88 Bq (0.306 and 0.294 nCi), which was below the NRC reporting threshold of 185 Bq (5 nCi). The NAD was determined to have a compromised source and was removed from service. Attempts were made to transfer the NAD to the Idaho National Laboratory, but no documentation was found to verify that the transfer occurred. An exhaustive search failed to locate the NAD and the university determined that it was unaccounted for on 10/12/2017. The NAD may have been placed into a nuclear waste stream and transferred in 2006 or 2011 with other waste, but there are no supporting records. To prevent recurrence, efforts were initiated to return the remaining 13 NADs and another similar source to the Idaho National Laboratory. Inventory practices and personnel responsibilities were updated.

Item Number 170538 - A university reported the loss of a package that contained six U-235 metallic sources/metal fuel foils. The metal fuel foils contained 116.92 kBq (3.16 μ Ci)/1.437 grams of 40% enriched U-235 and 26.64 kBq (0.72 μ Ci)/2.137 grams of U-238. The package was received and surveyed on 10/30/2017. The radiation levels were 0.9 μ Gy (90 μ rad) on contact and 0.11 μ Gy (11 μ rad) at one meter. The package was delivered to the office of the professor who ordered it. The package was placed under a desk, next to a trash can and a recycle can. The professor forgot about the package and failed to deliver it to the research area. The professor last saw the package on 11/3/2017. On 11/6/2017, the professor noticed that the package was missing and reported the loss to the RSO on 11/7/2017. The garbage in the professor's office had been collected on the evening of 11/6/2017 and placed into a dumpster. The dumpster was emptied into the normal waste stream on 11/7/2017. A search of all of the

dumpsters failed to locate the package. On 11/8/2017, the Radiation Safety Committee vice chair issued a stop work order for involved laboratories until an investigation was completed and corrective actions implemented. The RSO will retrain the authorized user on proper source security, custody responsibilities, and appropriate use/storage locations. The Radiation Safety Office will no longer deliver radioactive material (RAM) packages to the authorized user's office. The Radiation Safety Manual will be amended to include the requirement that all RAM packages are to be delivered to an approved location. The Receipt of Radioactive Material Procedure form will be amended to include an authorized user or designee acknowledgment of receipt. Further, larger RAM warning labels will be affixed to the exterior of RAM packages before RSO staff transport packages to the authorized user's laboratory.

Item Number 180177 - The Carpentersville, Illinois, Police Department reported finding a radioactive source on 4/5/2018 abandoned near a dumpster in a residential area. The police used the manufacturer's label and emergency contact information on the package to notify the manufacturer. The manufacturer's RSO arrived on scene and confirmed that the source was a Ge-68 phantom source. The RSO took possession of the source and the scene was cleared. In coordination with the California Health and Human Services Agency (CHHSA), it was determined that the source was originally supplied to a hospital in Pasadena, California. The hospital had their PET/CT unit serviced on 11/27/2017 and three sources were removed by a service company (based in Lake Zurich, Illinois) and shipped to a source disposal company in Burbank, California. The three sources removed were the abandoned 51.43 MBq (1.39 mCi) Ge-68 phantom source and two 42.18 MBq (1.14 mCi) Ge-68 rod sources. The Illinois Emergency Management Agency (IEMA) contacted the source disposal company who confirmed that they did not receive the sources. At that point, IEMA notified first responders and state and federal partners of the two additional missing sources. IEMA dispatched personnel to conduct gamma scintillator surveys of the area where the phantom source was found. The two missing rod sources were not located. IEMA informed CHHSA on 4/6/2018 that the service company does not possess a radioactive material license and is not authorized to pick up radioactive material. IEMA performed an investigation at the service company on 4/9/2018. According to the common carrier manifests and shipping receipts, the service company onsite technician packaged the three sources and transported them to the common carrier's drop off location on 12/7/2017. However, the shipper/recipient information was inadvertently reversed on the labels, resulting in the sources being shipped back to the service company in Lake Zurich, Illinois. The two packages arrived in Lake Zurich on 12/12/2017. On 12/13/2017, the service company again attempted to ship the sources to the source disposal company in Burbank, California. The two packages were again returned to the service company on 12/19/2017. At that point, the sources were stored in the service company warehouse for several months. The service company representative claims to have packaged and shipped the two packages back to the source disposal company in Burbank, California on or around 3/12/2018. The service company representative said this shipment did not have an electronic record. The common carrier has no record of the packages being picked up from the service company. Police found the abandoned Ge-68 phantom source at the dumpster adjacent to the home of the service company representative. The recovered source contained a decayed activity of approximately 7.84 MBq (212 µCi). Exposure rates were 0.8 mR/hour at one foot and 0.09 mR/hour at one meter. However, the unshielded contact exposure rate could be as high as 1.1 R/hour. Leak tests revealed no removable contamination. The two missing rod sources each contain a decayed activity of approximately 7.4 MBq (200 µCi). The manufacturer stated that if the sources are removed from their shielding, the exposure rate would be approximately 1 mR/hour at one foot and 100 µR/hour at one meter. There are no exposure concerns reported and efforts to recover the two remaining sources are ongoing. CHHSA is citing the hospital for loss of control of their Ge-68 sources by transferring them to a non-licensed facility, for not ensuring that the individual performing service was properly trained, and for failing to ensure that the individual did not receive radiation exposure above limits. IEMA implemented procedures to review the activities performed by PET/CT service providers.

Item Number 180227 - A steel company reported that a barge load of scrap from a recycling company set off their radiation monitor alarms on 4/17/2018. While offloading the scrap, a source of radiation was

discovered. The source of radiation appeared to be a Cs-137 source capsule stuck in a 0.5 inch diameter steel pipe approximately two inches in length. The highest radiation level was 5 R/hour at close proximity. The source was isolated. The origin of the source is unknown and no identifiable markings were noted. The estimated activity of the source was 1.11 GBq (30 mCi). The source was transferred to a radioactive waste broker for disposal on 4/30/2018.

Item Number 180429 - A construction services company reported that a moisture/density gauge was run over by construction equipment at a temporary job site in Monterey Park, California, on 9/7/2018. The gauge contained a 1.85 GBq (50 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source. The damage resulted in the loss and recovery of the Cs-137 source. Following the accident, the gauge operator notified his RSO. He sent photographs of the broken gauge handle and said that the source rod was bent. He retracted the source rod, secured the gauge inside the transport container, and transported the gauge to their permanent storage site. The RSO visually inspected the gauge on 9/9/2018 and instructed the gauge operator to transport it to a gauge service center on 9/10/2018. The service center discovered that the tip of the rod containing the Cs-137 source had broken off and was missing. The Am-Be source was in place. The RSO contacted the job site supervisor concerning the missing source and ensured that personnel were not working in the accident area. The gauge operator and RSO went to the accident site to search for the Cs-137 source. They located the source and used eight-inch long pliers to place it into shielding. The source was then transported to the gauge service center for evaluation and emergency leak testing. The California Health and Human Services Agency (CHHSA) investigated the incident. As part of their corrective actions, the construction services company purchased a radiation survey meter and will maintain annual calibrations, perform accident prevention actions, and provide emergency procedure training to all gauge operators. They also amended their emergency procedures such that the RSO will notify CHHSA immediately of an event involving significant damage to a gauge, and they will conform to regulatory reporting of gauges that have been damaged and could lead to radiation contamination or exposure. This event was classified as an EOP and MED event.

2.2.3 Events Recently Added to NMED That Occurred Prior to FY18

Twelve LAS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Category 1 Source Events None

Significant Events - Category 2 Source Events
None

<u>Significant Events - Category 3 Source Events</u> None

Events of Interest

Item Number 180091 - The Department of Defense, Defense Threat Reduction Agency (DTRA), reported the loss of a radioactive source at an offsite training location on 8/2/2017. While packing the vehicle at the conclusion of the training, the source, which was stored in an unmarked case, was inadvertently left on the roof of the vehicle. Upon arrival at the home office to return the source to its storage location, DTRA staff discovered that the source was missing. After a prompt and extensive search by DTRA, the source was recovered on 8/3/2017. There were no actual radiological consequences. The cause of the incident was the responsible individual did not follow DTRA transportation procedures. To prevent recurrence, restrictions were implemented on the use of licensed material at temporary job sites. The involved individual's authorization to use licensed material was removed pending review. DTRA instituted a two-person rule, instead of training being conducted by one person. Source-in-use procedures

were developed and other procedural changes were also implemented. DTRA instituted training for all personnel in safeguard procedures. The event was reportable to the NRC, but due to the nature of the licensed material, details of the event are contained in non-public documents.

Item Number 180343 - A plastic manufacturing company reported that two fixed nuclear gauges were destroyed in a fire on 12/3/2015. The gauges each contained a 5.55 GBq (150 mCi) Am-241 source. The incident was reported to the Illinois Emergency Management Agency (IEMA) during the 2018 annual source reconciliation. The company stated that the facility was completely destroyed in the fire and debris was hauled to a landfill. Site surveys by IEMA staff began on 8/2/2018. Building debris was found to still be onsite; only one load had been hauled away for recycling. The purchasing scrap yard was notified of the event. Survey efforts concluded with no identification of diffuse or discrete radioactive sources. The plastic company stated that immediately after the fire, site personnel were precluded from entering the site for two weeks. During that time, the site was illegally entered and all copper, scrap, and steel was stolen for recycling. They believe the two sources were either inadvertently disposed of during site cleanup or stolen and diverted to the recycling stream. No radioactive sources have been reported to IEMA or found during response to scrap facilities. Comprehensive surveys have mitigated the chances that the sources are still on site. Efforts to locate the sources at waste management or recycling facilities have not been productive. This even was classified as an EOP and LAS event.

2.3 Medical

2.3.1 Ten-Year Data

Figure 3 displays the annual number and trend of MED events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

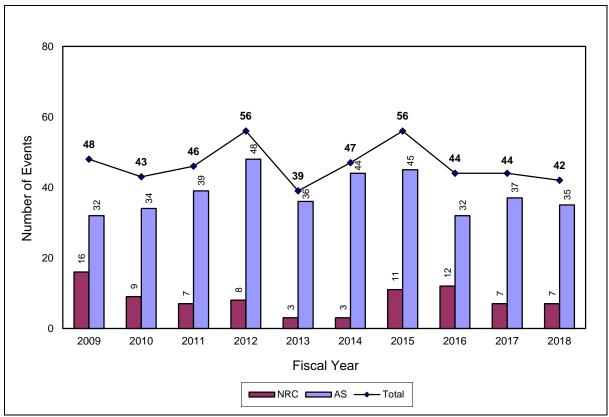


Figure 3. Medical Events (465 total)

Table 5 lists the number of MED events that were classified as Abnormal Occurrences (AOs) in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Note that recent events are considered potential AOs until they complete NRC's formal AO determination process and are reported in NUREG-0090. Potential AO events are included in Table 5. Also included are events involving doses to an embryo/fetus or a nursing child (reportable per 10 CFR 35.3047). By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as an "Other" event. However, they are included here for reference.

Table 5. Medical and Embryo/Fetus or Nursing Child - AOs or Potential AOs

		Fiscal Year									
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Medical	15	12	14	13	7	11	14	7	10	8	111
Embryo	2	2	1	1	2	1	1	1	0	0	11
Total	17	14	15	14	9	12	15	8	10	8	122

For this report, events classified as AOs (or potential AOs) are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.3.2 FY18 Data

Forty-two MED events occurred in FY18, eight of which were considered significant and classified as potential AOs.

Significant Events - AOs or Potential AOs

Item Number 180063 - An error occurred during a high dose rate (HDR) treatment to a patient's left breast using a Strut-Adjusted Volume Implant (SAVI) applicator. The incident involved an HDR unit and a 282.2 GBq (7.627 Ci) Ir-192 source. The error resulted in greater dose than prescribed to the skin of the breast, as well as less dose than prescribed to the target volume. The error was identified after the first of 10 fractions was completed on 1/29/2018; the remaining nine fractions were cancelled and the SAVI applicator was removed. During treatment planning on 1/26/2018, struts 2 and 6 of the SAVI applicator were mislabeled, which changed the physical orientation of the SAVI applicator during treatment. Instead of directing the radiation towards the target volume and away from the skin, the radiation was actually directed away from the target volume and towards the skin. A 1 cc volume of the patient's skin received 850 cGy (rad) instead of the intended 256 cGy (rad), a 0.1 cc volume skin received 1,542 cGy (rad) instead of the intended 282 cGy (rad), and a 0.03 cc volume of skin received 1,899 cGy (rad). Also, 90% of the target volume only received 56% of the prescribed dose of 340 cGy (rad). The patient and referring physician were notified of the event. The patient is at increased risk of developing acute and late significant skin toxicity. As of eight days following the event, no tissue effects had been observed. The cause of the event was determined to be misidentification of struts on the SAVI applicator during the treatment planning process, causing a discrepancy between the virtual and physical orientation of the applicator. Corrective actions included changing the policy to require a second physicist or physician to independently verify identification of catheter struts in the treatment planning system, developing a plan review checklist to include a second independent review of the treatment plan (including digitization of the catheter/struts), adding a plan review to the monthly audit, and educating all physicists and radiation oncologists on changes prior to any other HDR treatments.

Item Number 180074 - A patient who received three gynecological intra-cavity brachytherapy treatments experienced a skin reaction to the thighs. The incident involved a high dose rate (HDR) unit and a 264.18 GBq (7.14 Ci) Ir-192 source. The patient was prescribed three fractions of 400 cGy (rad) each, for a total of 1,200 cGy (rad) to a depth of 5 cm. The skin reaction was noticed during the third fraction on 1/24/2018. At that point, it was unclear if the skin reaction was related to the treatments. On 2/6/2018, the attending physician saw the patient and declared that the skin reaction was caused by the radiation treatments, because it had progressed to moist desquamation. The dose estimate for the patient's skin directly in contact with the surface of the internal catheter was between 5,154 and 8,555 cGy (rad). It appeared that most of the second fraction was not delivered to the intended treatment site due to applicator/catheter movement. The hospital assumed that the second fraction dose went entirely to the unintended site. The hospital believes that the catheter slid out of the cylinder applicator and ended up between the patient's thighs. The catheter was supposed to be fixed in place by a pressure coupling once the cylinder was assembled and the locking nut tightened. However, the locking nut was likely too loose, which allowed the catheter to slide out. The cause of the event was either patient intervention and/or medical staff inattention as either the applicator slipped from the patient or the inner catheter was not tight, allowing the catheter to slide from the applicator prior to treatment. Medical staff involved with the treatment process were retrained on procedures, as well as the authorized user who assembled and placed the cylinder. The authorized user will double check all connections and placement prior to and at the end of treatment. A new cylinder with a new design was purchased to minimize the possibility of recurrence. A medical consultant was hired to review the incident. An inspection was also performed of the event.

Item Number 180093 - A medical event occurred on 2/19/2018 during a patient's first high dose rate afterloader treatment fraction utilizing 255.3 GBq (6.9 Ci) of Ir-192. The patient was prescribed to receive 500 cGy (rad) per fraction for five fractions. During digitization of the applicator's 13 channels, channel 12 was digitized twice. The digitization of channel 13 was inadvertently included in channel 12. There were no dwell positions in channel 13. Despite the mistake, the treatment plan in the planning system displayed the expected dose distribution to the critical organs and tumor. The dose-volume histogram also showed the expected values. One section of the planning screen that shows which dwell positions are activated clearly showed the extended length of channel 12 and no dwell positions in channel 13. However, the plan was approved by the physician and transferred from the planning computer to the treatment console computer. The plan, as viewed on the treatment console, showed the length of channel 12 extending 5.5 cm past the treatment site and no dwell positions in channel 13. The treatment was administered to the patient on 2/19/2018. When the patient returned on 2/21/2018 to receive the second fraction, the physicist identified that an error had occurred during the first fraction. The plan was reviewed by the medical physicist and prescribing physician. Two areas along the vaginal wall outside the targeted volume with a total combined volume of approximately 0.5 cubic centimeters received 500 cGy (rad), with 30% of that volume receiving 1,000 cGy (rad) or more. The hospital investigated the cause. The physicist involved in this event was not normally assigned to this location, but was experienced with this particular therapy. The event occurred due to rushing to complete the plan and export it to the treatment console to treat a patient that was experiencing discomfort (full bladder). The radiation team was assembled and the patient was taken to the radiation vault for treatment before plan preparations were completed. The second review of the plan was done in a hurried manner and the digitization error was overlooked. To prevent recurrence, every effort will be made by the hospital to provide a thorough second check of treatment plans by a physicist who has not worked on the plan. Each channel in an applicator will be carefully reviewed. The patient will not be brought to the treatment area until the plan is checked and exported to the treatment control computer and treatment data are verified with planned data. If any doubt arises, the treatment will be delayed until the problem is clarified. The patient and referring physician were notified.

Item Number 180252 - A patient developed skin erythema after being radioactively contaminated during a medical treatment on 5/25/2018. The 17-year-old pediatric patient was scheduled to receive 30.23 GBq (817 mCi) of I-131 metaiodobenzylguanidine (MIBG) for treatment of brain cancer. The dose administered measured 30.86 GBg (834 mCi) and was delivered over the course of 90 minutes. The dosage was delivered in a 30 ml syringe and infused via an automatic pump. The nuclear medicine technician present during the infusion saw a small amount of blood, but nothing unusual other than that was noted. However, upon completion of the infusion, radiation surveys revealed high activities of I-131 on the patient's clothing and bed linen. On 5/27/2018, the patient reported discomfort and reddening on the skin of his upper right thigh, which developed into an erythematous lesion and further into desquamation (grade 3) the next day. Radioactive contamination is believed to have been present on the patient's skin for 24 to 48 hours. Due to the large dosage of I-131 infused, medical staff were unable to detect the contamination until the patient developed erythema. Decontamination of the patient was not performed until the patient developed erythema. Based on measurements, nuclear medicine imaging, and the patient's clinical symptoms, the dose to the skin was estimated to be between 50,000 and 120,000 cGy (rad) to a 15 cm² area. Radiation safety staff consulted with the Radiation Emergency Assistance Center/Training Site (REAC/TS) to verify dose calculations. Calculations of the activity in the waste and the exposure rate from the patient in previous treatments estimated the activity delivered at 22.68 GBq (613 mCi). It was calculated that approximately 7.77 GBq (210 mCi) went to the waste. The authorized user was informed and notified the patient's parents and referring physician. The Pennsylvania Department of Environmental Protection performed a reactive inspection on 6/7 and 6/13/2018. A leak in the delivery system was caused by a failure of the Spiros connection in the infusion line. The patient had been disconnected from the infusion pump at the Spiros tube to use the lavatory part way through the procedure. Policies and procedures relating to patient contamination and decontamination during dose

administration were incomplete. A multidisciplinary I-131 MIBG team with representatives from nuclear medicine, radiation safety, nursing, and oncology was established. That team will meet regularly to review and update policies and procedures for MIBG therapies. Corrective actions include the use of absorbent material under the administration line over the patient's body, a change to the administration procedure to require that the infusion not be stopped unless medically necessary, planned implementation of continuous patient observation during administration including the use of portable video monitoring, a new procedure to address patient fluid management, a review of the infusion system with focus on the Spiros connector, and additional training. Patient specific decontamination procedures and radiation safety incident response procedures were developed.

Item Number 180268 - A patient received a Y-90 microsphere dose to the wrong lobe of the liver. The patient was prescribed to receive 1.35 GBq (36.38 mCi) to the right lobe on 6/6/2018. A subsequent CT scan revealed that the microspheres were actually delivered to the left lobe. The right lobe should have received a dose of 4,874 cGy (rad), but the left lobe received a dose of 11,080 cGy (rad). The cause was human error. The catheter was accidentally placed in the left hepatic artery instead of the right hepatic artery. Corrective actions included procedure modifications.

Item Number 180281 - Brachytherapy seeds were incorrectly placed during a prostate implant procedure on 6/14/2018. Prior to the procedure, doctors inserted a Foley catheter into the patient. The catheter balloon was inflated in the prostatic-urethra, instead of the bladder as intended. Using the catheter balloon as a guide, the patient was implanted under ultrasound guidance with 54 Pd-103 seeds that contained a total activity of 4 GBq (108.167 mCi). The ultrasound guidance was compromised because it defaulted to a magnified view of the surrounding area. The patient returned on 6/15/2018 for a CT scan to verify seed placement. The CT scan revealed that 32 of the seeds had been implanted outside of the prostate. In addition, only 51 of the seeds were located. The three missing seeds are believed to have been passed via stool prior to the patient's follow up CT scan. An additional seed is believed to have also been passed as a result of an enema during the follow up exam post CT scan. The patient was prescribed a dose of 12,500 cGy (rad) to the entire prostate gland volume (18.3 cm³), but the treatment only delivered 1.000 cGv (rad) to the prostate volume. The NRC Event Notification stated that the rectal tissue received 18,677 cGy (rad) and that no rectum dose was anticipated. However, a follow-up report stated that the rectum was intended to receive no more than 18,000 cGy (rad). The hospital determined that there is a risk of radiation damage to the rectum and surrounding tissues. The patient and authorized user were notified on the day of discovery and a special investigation was performed by the hospital. The Utah Department of Environmental Quality performed a special onsite inspection. The event was caused by a poorly placed Foley catheter, staff failing to properly locate the Foley catheter, and proper anatomy for guidance within a magnified ultrasound image. The hospital implemented specific training for physicians and other participating staff to prevent recurrence. The ultrasound manufacturer was contacted and the default magnification of the ultrasound unit was changed to a value that allows for initial visualization of the relevant prostate anatomy in its entirety. The hospital also implemented policy changes. Prior to the insertion of the seed needle, using the widest field of view possible, both the sagittal and axial ultrasound images will be obtained to validate Foley catheter placement. Both the authorized user and the medical physicist will audibly concur that image quality is sufficient for proceeding with the implant and the medical physicist will document that in their operative reports or treatment records. After the first seed is implanted in the patient, a fluoroscopic image will be obtained to validate that the relative position of the seed and the Foley catheter are as anticipated.

Item Number 180334 - A patient prescribed to receive six fractions of high dose rate (HDR) brachytherapy treatment for vaginal cancer, at 350 cGy/fraction (rad/fraction), actually received 2,100 cGy (rad) during the first fraction on 7/10/2018. The HDR unit contained a 222 GBq (6 Ci) Ir-192 source. This event was discovered when the medical physicist noticed that the total treatment value was incorrectly entered into the treatment planning system. The radiation oncologist was notified and he notified the referring physician and patient on 7/11/2018. The overall brachytherapy plan was modified

and the volume treated in the first fraction was considered complete; the patient will not receive further treatment. The radiation oncologist plans to closely follow the patient and make all possible interventions to minimize potential adverse effects. The Texas Department of State Health Services conducted an onsite investigation on 8/6/2018. The hospital indicated that human error and poor decision making caused the event. A busy work schedule that day led to starting the patient's first treatment fraction after normal working hours. Despite the unavailability of a second medical physicist to independently review the dose/fraction entered into the treatment planning system, the medical physicist made the decision to develop the treatment plan, transfer the plan to the treatment console, and conduct the procedure without ensuring a second check of the plan parameters was performed in accordance with hospital procedure. The hospital subsequently modified their procedures to require that a second medical physicist conduct an enhanced independent review of the treatment plan at the treatment planning console, the treatment team to conduct an enhanced time-out at the treatment planning console to check the patient's name, dose, prescription, source activity, and prescription number, and a medical physicist check that the exported treatment plan from the planning console matches the plan at the treatment console. Staff training will emphasize complete adherence and compliance to the updated HDR policy and procedures. Treatment team enhanced time-out training will be completed before the end of October 2018. All other corrective actions were incorporated and compliance was achieved in August 2018.

Item Number 180377 - A patient received a dose of 29,400 cGy (rad), instead of the prescribed dose of 13,600 cGy (rad), during a Y-90 microsphere treatment on 8/9/2018. The patient received an activity of 3.841 GBq (103.8 mCi). On the previous day, the nurse manager verified that the patient's intended Y-90 dose had been received by nuclear medicine. However, nuclear medicine received a second Y-90 dose on 8/9/2018 that was to be used for a different patient the following week (after decay). The nuclear medicine technician took that second dose, opened it, and measured it without checking the printed code on the shipping box, which included the patient's initials. The dose calibrator reading and a decay calculation performed based on the manufacturer's calibration data sheet agreed within 10%. However, the results were not compared with the written directive before taking the second (incorrect) dose to interventional radiology for the pre-administration measurements. The dose was administered to the patient. The interventional radiologist was informed of the event as soon as the post-administration calculations were confirmed. The patient was informed and sent to nuclear medicine to be imaged. That scan showed very good containment within the liver. The physician stated that the patient should actually tolerate the dose and that he had considered administering a high ablation type of dose of greater than 20,000 cGy (rad). The hospital will add a dose verification step when the dose is in interventional radiology during the preliminary set-up with the nurse manager. Other steps will be put in place after further discussion. The incident is being entered into the hospital's notification system and will likely receive further review at that level.

Events of Interest

Item Number 180104 - A patient received Y-90 microspheres to the wrong treatment site. The patient was prescribed to receive 1,420.8 MBq (38.4 mCi) on 2/19/2018 to treat metastatic liver carcinoma. The arterial access had been previously mapped and the administration appeared to go normally. The post-scan appeared normal with a small uptake to the bowel. However, the patient returned to the facility on 2/23/2018 complaining of pain in the abdomen, so a number of diagnostic studies were performed. Erythema on the patient's abdomen was noted. Another authorized user reviewed the post-scan and felt that approximately one-third [481 MBq (13 mCi)] of the microsphere dose had migrated up a venous ligament and lodged in the abdominal wall. The hospital believes that the dose to the patient's abdomen was above 55 cGy (rad) but less than 1,000 cGy (rad). The exact dose may be impossible to determine given the nature of the radionuclide and the uneven distribution of the microspheres. The RSO was notified of the incident on 3/1/2018. The incident occurred because the physician had difficulty visualizing the arterial access to the tumor. That was due to the patient's pre-existing kidney impairment, which limited the amount of radiographic contrast that could be used. It appears that the microcatheter was not advanced far enough into the correct artery to ensure that all of the dose went to the intended

location. The hospital monitored the patient closely to determine the effects of the dose. As of 3/16/2018, the pain had subsided and no other adverse effects were reported. Corrective actions included installation of a second monitor so that the physician can immediately refer to the original arteriogram without switching between tasks. That will greatly increase confidence in correct placement, even if image quality is somewhat impaired. In the event that the procedure needs to be performed on another patient with impaired kidney function, prophylactic measures will be taken prior to implant (such as bicarbonate hydration protocols to allow the use of more contrast). The referring physician, patient, and microsphere manufacturer were notified of the event. The Georgia Department of Natural Resources performed a reactive inspection on 3/8/2018.

Item Number 180174 - A high dose rate (HDR) brachytherapy treatment using a 159.84 GBq (4.32 Ci) Ir-192 source was administered to the wrong site. The patient received treatment to a breast keloid in two fractions of 600 cGy/fraction (rad/fraction) on 3/6 and 3/7/2018. The patient contacted the oncologist when a skin/tissue reaction was discovered on 4/2/2018. The reaction was not an anticipated response to the treatment plan. It was determined that the physicist used the incorrect methodology (tip end instead of connector end) for delivering the treatment plan. An estimated 1,200 cGy (rad) dose was directed to the wrong treatment site (lateral left breast skin). The patient was informed of the error on 4/4/2018. Corrective actions included providing additional training to personnel. The patient will be evaluated by the oncologist during the first week of April 2018.

Item Number 180257 - A patient's skin was contaminated with F-18 during a PET scan performed on 4/4/2018. At the time of injection, approximately 555 MBq (15 mCi) of F-18 was inadvertently squirted onto the patient's shirt. Since the first dose was not administered as intended, a second dose of 555 MBq (15 mCi) was administered to the patient. The patient then rested for one hour and was imaged. The patient was released from the scan room, discharged, and went to the cafeteria. The study physician reviewed the images, found them inadequate due to external contamination, and ordered that the images be repeated. The patient was located in the cafeteria and returned to the nuclear medicine department. The patient's shirt was removed and he was reimaged approximately one hour after the start of the first scan, which was approximately two hours after his shirt was contaminated. The second images were deemed appropriate. The RSO learned of the event on 5/15/2018 and began an investigation. Initial patient skin dose estimates revealed 200 cGy (rad). On 5/31/2018, the patient's skin dose was estimated at approximately 280 cGy (rad) to 100 cm² of tissue on the patient's torso; the uncertainty in the skin dose calculation is great. The study physician notified the referring physician of the event. The patient was not notified, but the patient was aware of the spill and that his shirt was kept for decay. Notice will be sent to the patient offering the ability to obtain a written description of the event. Training will be provided to all nuclear medicine employees regarding spills. This event is classified as an MED and RLM event

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as "Other" events. However, it is appropriate to also discuss these events in this section. None of these events occurred in FY18.

2.3.3 Events Recently Added to NMED That Occurred Prior to FY18

Five MED events and no embryo/fetal dose events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of the MED events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - AOs or Potential AOs None

Events of Interest None

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs None

2.4 Radiation Overexposure

2.4.1 Ten-Year Data

Figure 4 displays the annual number and trend of EXP events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

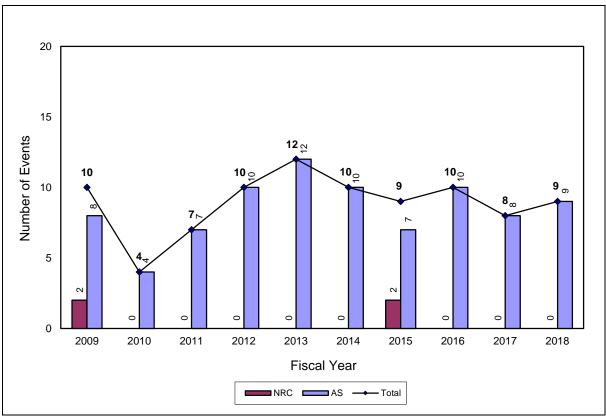


Figure 4. Radiation Overexposure Events (89 total)

The significance of individual EXP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate or 24-hour reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 6 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 6. EXP Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Immediate	0	0	1	1	0	0	0	1	0	1	4
24-Hour	1	1	0	4	1	3	4	1	2	2	19
30-Day	9	3	6	5	11	7	5	8	6	6	66
Total	10	4	7	10	12	10	9	10	8	9	89

2.4.2 FY18 Data

Nine EXP events occurred in FY18, three of which were considered significant.

Significant Events - Immediate Reporting

Item Number 180352 - A radiographer received a radiation overexposure. The dosimetry processor stated that the radiographer's dosimeter read 37.5 cSv (rem) for the month of June 2018. The dosimeter report indicated that the exposure was irregular. The radiographer stated that he had not lost his badge, but had left it in the radiography truck a few times on his days off. The radiographer was removed from all duties that would result in any additional exposure to ionizing radiation. The radiographer's July dosimeter was sent to the dosimetry processor for analysis. The radiographer's co-worker's dosimeter revealed normal results. The company RSO contacted the Radiation Emergency Assistance Center/Training Site (REAC/TS) for assistance. The RSO believed that the exposure was to the badge only and stated that the radiographer had not displayed any signs of a high exposure. On 8/14/2018, the company received blood sample results from REAC/TS that indicated an exposure of 44 cGy (rad). The company conducted a complete investigation. The radiographer confirmed that his pocket dosimeter had previously gone offscale and he failed to report it. He could not recall when or where, but confessed to placing a fabricated reading on the daily report. The radiographer explained that he did not always use a survey meter to check if the source was retracted into the fully shielded position. The radiographer's disciplinary actions are still pending. The company has informed all radiography staff to ensure that correct pocket dosimeter readings are obtained and written on the daily sheets. The radiographer used two exposure devices during the month of June 2018, with a 2.44 TBq (65.95 Ci) Ir-192 source and a 0.81 TBq (21.89 Ci) Ir-192 source, respectively. This event was classified as a potential AO.

Significant Events - Within 24-Hour Reporting

Item Number 180154 - A radiographer trainer received a whole body radiation exposure of 5.769 cSv (rem). Further investigation revealed that the radiographer's assistant received a whole body exposure of 4.583 cSv (rem). An investigation indicated that the radiographers received the exposures during operations at a refinery in Richmond, California, on 3/14/2018. The radiographers were using a radiography exposure device with a 3,289.3 GBq (88.9 Ci) Ir-192 source. The overexposure likely resulted from the failure to fully retract the source into the shielded position following an exposure. A confirmatory radiation survey was not performed following that exposure and the self-reading dosimeters were not properly utilized. Both individuals were removed from radiographic operations. The exposure device was inspected and did not show any sign of defect or damage. Corrective actions include improved personnel training and audits, including increasing the frequency of the audits. As of 3/29/2018, this incident had a final International Nuclear Event Scale rating level of 2.

Item Number 180187 - A radiographer received a whole body radiation exposure of 5.875 cSv (rem). On 4/6/2018, the radiographer was working at a fabrication shop using an exposure device with a 3,803.6 GBq (102.8 Ci) Ir-192 source. Following several shots at one location, the radiographer carried the exposure device, with the crank assembly and source guide tube still attached, to a different location. Prior to movement, the device was located under a large amount of piping. When the radiographer

grabbed the device, he inadvertently placed his hand on the locking mechanism and unlocked it. When he moved the device, the crank assembly rotated, causing the source to move six to ten inches out of the shielded position. The radiographer moved the device about five feet and held it for 15 seconds. He then worked near the device for five minutes, removing and setting up new film. He never heard his rate meter alarm due to excessive noise in the building. It was only after he walked out of the shooting bay that another individual heard the alarming rate meter. The radiographer went back into the bay, rotated the crank assembly one full turn, and retracted the source into the fully shielded position. The exposure device and crank assembly were tested several times and appeared to be working normally. No other person appeared to have received any significant radiation exposure. The root cause was poor placement of the exposure device with a source guide tube that was too short. The company conducted training with all workers, researched additional alarm systems for the bay, looked into better rate meter alarms, and reassessed source guide tube sizes to ensure exposure devices can be placed in better locations. The involved radiographer was removed from his duties. As of 5/10/2018, this incident had a final International Nuclear Event Scale rating level of 2.

Events of Interest

Item Number 180006 - A nuclear medicine employee had unusually high readings on his dosimeter over several months. The employee's July 2017 dosimeter revealed 4.9 mSv (490 mrem) DDE, his August 2017 dosimeter revealed 4.9 mSv (490 mrem) DDE, his September 2017 dosimeter revealed 8.92 mSv (892 mrem) DDE, his October 2017 dosimeter revealed 128.7 mSv (12,870 mrem) DDE, and his November dosimeter revealed 1.66 mSv (166 mrem) DDE. The California Health and Human Services Agency is investigating to determine if the dosimetry results are reflective of the exposure to the individual. The medical center does not know how the employee received the high exposure readings, but believe the dosimetry results do not reveal a real exposure to the employee. Corrective actions included implementing a new policy which states that all employees must place their dosimeters in a designated location.

Item Number 180017 - A medical device company employee received a skin exposure to the left extremity of 71.865 cGy (rad) during the biweekly monitoring period of 11/6 through 11/19/2017. The company was notified of the overexposure on 12/1/2017. They investigated and attributed the dose to one of two instances that occurred during the monitoring period. In the first instance, the technician worked a non-routine job cleaning and rebuilding the central region of a cyclotron in order to return the cyclotron to operation. That task took approximately two hours. The technician was in a high radiation area and others that worked the same job had high exposures, but no one else exceeded annual limits. In the second instance, the technician had difficulty operating the manipulator arms and pneumatic screwdriver within a hot cell. Without contacting health physics or cyclotron management, he decided to remove 10 screws in the target rail of the hot cell by hand. He held the target rail with his left hand and removed the screws with a screwdriver with his right hand. The projected activity on that day was 2,316.57 GBq (62.61 Ci) and the job took one to five minutes. The Georgia Department of Natural Resources performed a reactive inspection on 1/10/2018. It was determined that the overexposure resulted from the technician's intentional deviation from established procedures and protocol. The technician stated that the target drop work is infrequent. On this particular job, instead of asking another technician or the health physicist for assistance, he manually removed the screws from the target with regular gloved hands; he did not use lead lined gloves. The technician also received a whole body exposure of 1.85 mSv (185 mrem) and 4.749 cGy (rad) to the skin of the right extremity. Three other workers received whole body exposures of up to 3.64 mSv (364 mrem) and up to 1.643 cGy (rad) to their extremities. Retraining was scheduled for 1/11/2018 and new procedures were developed. As of 1/19/2018, this incident had a final International Nuclear Event Scale rating level of 2.

2.4.3 Events Recently Added to NMED That Occurred Prior to FY18

No EXP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Note that this data may differ from the associated Appendix

D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate Reporting

None

Significant Events - Within 24-Hour Reporting

None

Events of Interest

None

2.5 Release of Licensed Material or Contamination

2.5.1 Ten-Year Data

Figure 5 displays the annual number and trend of RLM events that occurred during the 10-year period. The trend analysis determined that the Total and NRC-regulated events represent statistically significant decreasing trends (indicated by the trend lines). However, the Agreement State-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line).

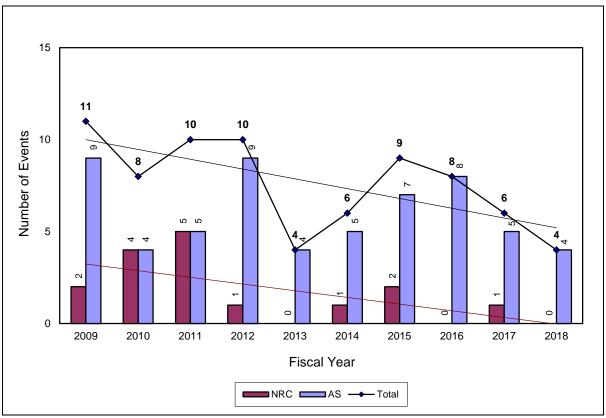


Figure 5. Release of Licensed Material or Contamination Events (76 total)

The significance of individual RLM events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 7 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 7. RLM Events Classified by CFR Reporting Requirement

					Fisca	al Year					
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Immediate	1	2	0	2	1	1	0	1	3	1	12
24-Hour	6	4	9	6	2	3	9	7	3	3	52
30-Day	4	2	1	2	1	2	0	0	0	0	12
Total	11	8	10	10	4	6	9	8	6	4	76

2.5.2 FY18 Data

Four RLM events occurred in FY18, one of which was considered significant.

Significant Events - Immediate Reporting

Item Number 180257 - A patient's skin was contaminated with F-18 during a PET scan performed on 4/4/2018. At the time of injection, approximately 555 MBq (15 mCi) of F-18 was inadvertently squirted onto the patient's shirt. Since the first dose was not administered as intended, a second dose of 555 MBq (15 mCi) was administered to the patient. The patient then rested for one hour and was imaged. The patient was released from the scan room, discharged, and went to the cafeteria. The study physician reviewed the images, found them inadequate due to external contamination, and ordered that the images be repeated. The patient was located in the cafeteria and returned to the nuclear medicine department. The patient's shirt was removed and he was reimaged approximately one hour after the start of the first scan, which was approximately two hours after his shirt was contaminated. The second images were deemed appropriate. The RSO learned of the event on 5/15/2018 and began an investigation. Initial patient skin dose estimates revealed 200 cGy (rad). On 5/31/2018, the patient's skin dose was estimated at approximately 280 cGy (rad) to 100 cm² of tissue on the patient's torso; the uncertainty in the skin dose calculation is great. The study physician notified the referring physician of the event. The patient was not notified, but the patient was aware of the spill and that his shirt was kept for decay. Notice will be sent to the patient offering the ability to obtain a written description of the event. Training will be provided to all nuclear medicine employees regarding spills. This event is classified as an MED and RLM event.

Events of Interest

Item Number 180363 - A radioactive material processing center reported that an unplanned contamination event occurred on 7/26/2018. During the process of cement solidification of shredded filter material, the mixing unit auger became stuck. Technicians, through the use of various manual and air tools, were able to remove the blockage and resume the solidification process. The unit was run again with only a cement mixture and no filter media to create a cap in the disposal container. Upon completion of that procedure, a crane operator entered the containment area to remove the filter media hopper from atop the unit. He had forgotten his hard hat and left the containment area and the building to retrieve it. Upon entering the personnel contamination monitor (PCM), he set off the alarm. The RSO was contacted and all remaining personnel exited the building and were found to be contaminated. All doors to the contaminated building were locked, all operations equipment was placed in the off position, and the building was secured. Building access was restricted. The plant manager stopped all work at the site and informed his chain of command. The total estimated activity was 74 MBq (2 mCi), with the primary radionuclide being Co-60 (at 90%), with Mn-54 and Sb-125 as other contributors. A detailed survey to assess the extent of contamination showed generally distributed contamination on the horizontal surfaces within the building. The maximum contamination level was 800,000 dpm/100 cm². Seven personnel exhibited generally distributed contamination of varying amounts on their exterior clothing and/or shoes and had indications of inhalation of radioactive material. All showered in the onsite decontamination room and then were

monitored with an extended count in the PCM. All were released with only gamma-related upper torso activity. Nasal swabs for the seven personnel were analyzed. Activities ranged from 51.8 to 802.9 Bq (1.4 to 21.7 nCi) of gamma related activity. Daily extended PCM counts continued for available personnel. Four individuals continued to exhibit activity. In addition, in vivo and in vitro bioassay measurements were initiated. Offsite laboratory bioassay measurement data was available about two to three weeks after the event and the internal dose assessment was completed. The highest estimated individual dose was approximately 2.9 mSv (290 mrem) CEDE and the lowest was approximately 0.15 mSy (15 mrem) CEDE. The building containment will remain restricted and work activities related to the encapsulation of material inside the containment were suspended indefinitely. The root cause of the incident was inadequate procedure implementation and training regarding radiological containment inspection and certification. Corrective actions included building containment program overhaul, upgrading procedures to include routine containment inspections and independent verification, highlighting operational procedures to require a verifying signature for proper ventilation alignment, installation of alarming differential pressure gauges on HEPA filter units, reviewing the current application of constant air monitors against problematic conditions, reviewing and upgrading shield frisking stations, implementation of a recurring refresher training program in addition to the recertification training programs, and conducting an all hands stand down to communicate priorities.

2.5.3 Events Recently Added to NMED That Occurred Prior to FY18

Two RLM events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate Reporting None

Events of Interest

None

2.6 Leaking Sealed Sources

2.6.1 Ten-Year Data

Figure 6 displays the annual number and trend of LKS events that occurred during the 10-year period. The trend analysis determined that the data do not represent statistically significant trends (indicated by the absence of trend lines).

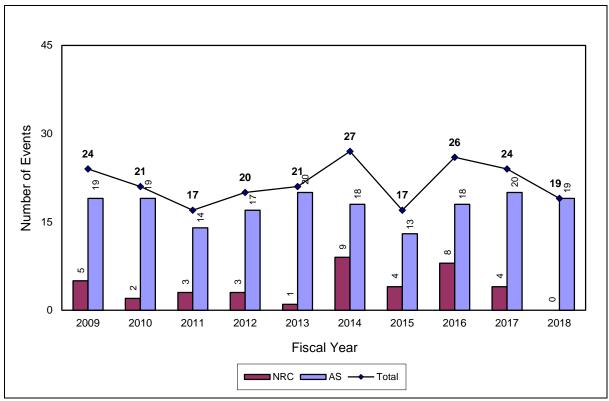


Figure 6. Leaking Sealed Source Events (216 total)

It is not possible to discern the significance of LKS events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). There are essentially no immediate or 24-hour reporting requirements for leaking sources. The exception is 39.77(a), which is an immediate report to the NRC Regional office of a ruptured well logging source. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.6.2 FY18 Data

Nineteen LKS events occurred in FY18, none of which were considered significant.

Significant Events

None

Events of Interest

None

2.6.3 Events Recently Added to NMED That Occurred Prior to FY18

One LKS event was recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. This event was not considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and

subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events None

Events of Interest

None

2.7 Equipment

2.7.1 Ten-Year Data

Figure 7 displays the annual number and trend of EQP events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

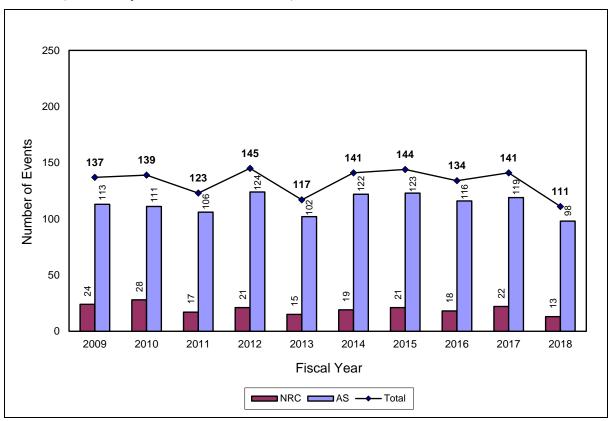


Figure 7. Equipment Events (1,332 total)

It is not possible to discern the significance of EQP events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5) because essentially all of the CFRs associated with EQP events require reporting within 24-hours. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.7.2 FY18 Data

One hundred eleven EQP events occurred in FY18, none of which were considered significant.

Significant Events

None

Events of Interest

Item Number 170505 - A gamma knife unit malfunction occurred on 10/20/2017 during patient treatment. The gamma knife recorded an error and the backup battery on the uninterruptible power source was low. This resulted in the gamma knife pausing and returning the source to the shielded position. The patient received approximately one third of their prescribed dose. The service provider was contacted and was

scheduled to report to the hospital on 10/23/2017 to replace the backup battery. This event was classified as an EQP and MED event.

Item Number 170563 - An oncology clinic reported the potentially serious malfunction of a universal stump applicator set. The malfunction allowed the high dose rate brachytherapy source guide tube to extend out of the front of the holder when pressure was applied, allowing the source to extend beyond the intended treatment area. The incident was discovered during pre-treatment imaging with a dummy source. Previous use of the universal stump applicator set was limited to a different 2.5 cm cylinder that did not display a similar malfunction. The universal stump applicator set was returned to the manufacturer for evaluation. Subsequent investigation confirmed that no misadministrations occurred. The manufacturer concluded that there was no device/equipment failure; the equipment was adequate as designed, but required an updated instruction set. The instructions should include direction on checking the tightness of the collet. The new instruction set should be available by March or April 2018 and will include language to perform a secondary test, which requires holding the applicator and applying pressure to the rigid guide tube in an attempt to force it forward of the applicator. The Illinois Emergency Management Agency (IEMA) recommended additional procedures to ensure that use of the device does not result in the guide rod extending past the applicator. However, the oncology clinic may discontinue use of the applicator altogether. Corrective actions were identified and implemented. IEMA staff performed an onsite investigation on 1/22/2018 and met with the RSO to further discuss the incident. Three additional instances of the guide tube extending past the applicator have been reported to the manufacturer as of 2/5/2018.

Item Number 170568 - An oil refinery reported that two fixed nuclear gauges were involved in a fire on 11/28/2017. Each gauge contained a 74 GBq (2 Ci) Cs-137 source. A consultant stated that they could not gain access to the gauges until 11/30/2017. The gauges were located 20 to 30 feet above the ground and did not create an exposure risk to any individual. The source holders were visibly intact, but black with soot. Both gauges were surveyed. Radiation readings on one gauge revealed a localized spot on the lower left-hand location of the shield at 180 mR/hour on contact, with 14 mR/hour at one foot. Additional shielding was attached to that lower left-hand location to reduce the dose rate to 3 mR/hour at one foot. Radiation readings on the other gauge were normal. Sealed source leak tests were performed and revealed negative results (less than 3.7 Bq or 0.0001 μ Ci). The sources will be removed by the consultant and disposed of by the second quarter of 2018. New sources and source holders will be purchased and installed as well as added to the license in the coming months.

Item Number 170578 - An irradiation service company reported that one of three panoramic irradiator Co-60 source racks became stuck in the up position at on 12/8/2017. A worker noticed an unload fault on the system, indicating that the rack was stuck. The worker called maintenance to try to correct the problem. The RSO was notified of the event and then notified the corporate RSO. Workers were able to enter the penthouse to correct the problem and lower the source rack back into the pool. The workers found that the carrier had a broken metal hinge. They checked all of their other carriers and replaced a total of two carrier doors. The company established a preventative maintenance schedule. The NRC Registry of Radioactive Sealed Sources and Devices indicates that the source rack contains a maximum Co-60 activity of 629 TBq (17,000 Ci).

Item Number 180031 - An oil refinery reported that a fixed nuclear level gauge that contained a 3.7 GBq (100 mCi) Cs-137 source was involved in a fire on 1/3/2018. The source holder was intact for the most part, with the exception of a degraded/melted opening in the shielding. The radiation exposure level from that opening was 30 mR/hour at one foot. A service company was contacted and responded to the facility. They locked the shutter, secured the device, placed it in a storage container, and isolated the storage container. Some additional lead was placed over the opening and the exposure level was reduced to approximately 4 mR/hour. The storage container was placed behind a radiation-labelled barricade. The Cs-137 source did not appear to be damaged or compromised. The RSO performed wipes on the device and the wipes were sent out for analysis. The gauge was subsequently shipped for disposal.

Item Number 180119 - A mining company reported that an intentionally set fire damaged a fixed nuclear gauge on 2/14/2018. The gauge contained a 7.4 GBq (200 mCi) Cs-137 source. The gauge shielding material was degraded, causing elevated radiation levels. Maximum radiation levels of 1.5 R/hour on contact, with 700 mR/hour at six inches, and 40 mR/hour at one foot were noted. The gauge was secured and isolated pending disposal. Leak test results were negative. The gauge was transferred to a radioactive waste broker on 3/23/2018 for disposal.

Item Number 180167 - A radiography services company reported the inability to retract a 2.85 TBq (77 Ci) Ir-192 radiography source into an exposure device. Radiography was being conducted on an offshore platform at the 10-foot level on 3/31/2018. During the first exposure, the radiographer was unable to retract the source into the shielded position and observed that the guide tube had disconnected from the exposure device. After several failed attempts to retract the source, the radiographer lifted the guide tube to align the source drive cable while the assistant radiographer retracted the source. The radiographers then shut down the operation and called their RSO. A re-enactment of the event showed that it took approximately seven seconds to complete the source retrieval. The radiographer's deep-dose equivalent to the whole body was calculated to be 1.575 mSv (157.5 mrem). The RSO calculated a radiation exposure to the radiographer's hand at 6.3 mSv (630 mrem). The event was caused by a dirty guide tube quick connector. After cleaning the part, it worked as designed. All radiographers were reminded of the importance of equipment inspections before and during use, daily maintenance of equipment, and removing equipment from service when it is not operating as designed. All radiographers were also reminded of the requirements for source retrieval. Offshore darkrooms were supplied with lead shot and a lead sheet to be used for temporary shielding on any unshielded radiography source.

Item Number 180184 - A patient received dose to an unintended site when a high dose rate (HDR) brachytherapy source did not fully retract at the completion of a treatment fraction on 3/28/2018. The incident involved a 276.85 GBq (7.4824 Ci) Ir-192 source. The intended treatment site was the top five cm of the surface of the vagina. The prescribed dose of 2,100 cGy (rad) was to be administered through three fractions at 700 cGy (rad) each. At the completion of a fraction, the source remained in the transfer guide tube about five cm from the cylinder transfer guide tube connector. The source remained in that position, between the patient's thighs, for approximately five minutes, resulting in a dose of about 100 cGy (rad) to the thighs. It was determined that the source wire was bent near the source, which is suspected to be the reason that the source did not fully retract. The California Health and Human Services Agency conducted a site visit between 4/12 and 4/24/2018 to meet with personnel to gain a better understanding of incident details, especially concerning the delay in removing the source from the immediate vicinity of the patient, the delay in reporting the event to the RSO, and to better understand the reason that the source did not fully retract. Corrective actions included modifications to the risk management reporting system to require RSO notification, refresher training with the manufacturer, and additional radiation safety training. All written emergency procedures were reviewed for accuracy and reviewed with staff. The HDR unit was serviced by the manufacturer on 3/29/2018. A new Ir-192 source was installed on 4/2/2018. This event was classified as an EQP and MED event.

Item Number 180200 - An irradiation service company reported the failure of the source rack drive mechanism involving a panoramic irradiator. The irradiator faulted with a "source pass cylinder fault" on 4/21/2018. Source rack #1 moved to the safe position in the pool, but source rack #2 remained in the raised position. The maintenance manager was notified of the situation. After evaluating the problem with the rack, he found that air from the source rack #2 hoist cylinder was not being released through the associated solenoid valves. The operators loosened a pipe fitting and let air slowly bleed from the rack hoist cylinder. That brought rack #2 into the fully lowered position. The maintenance manager removed the solenoid valves and took them to the maintenance shop. There was no debris or water found in the valves. Both valves were replaced. The maintenance manager restarted the irradiator and after one cycle stopped the irradiator to test the valves. The source racks lowered into the pool as designed. The

solenoid valve vendor will be contacted on 4/23/2018 and backup/replacement valves will be ordered. Annual replacement of the valves will be added as a preventative maintenance task.

Item Number 180260 - A radiography services company reported the inability to retract a 1.85 TBq (50 Ci) Ir-192 source into a radiography exposure device on 5/31/2018. The crew was working in a remote area in West Texas (25 miles southwest of Jal, New Mexico, and five miles inside Texas), when they could not get the source to go past the exposure device inlet nipple. A radiographer disconnected the guide tube from the exposure device and saw that the source was not in the shielded position. The radiographer would have been in contact with the guide tube for three to five seconds. After a few attempts, the crew contacted their company and an individual authorized to recover sources was sent to the site. A second individual from the State of New Mexico also responded. The retrieval team separated the guide tube from the exposure device using long tongs. They could see the source sticking out of the shield at the threads on the inlet port. They attempted to push the source into the exposure device using a long set of pliers, but could only push the source partially into the device because of the size of the pliers. A second attempt to push the source in using the device's plug was successful. The source was locked in the fully shielded position. It took about 45 minutes to recover the source. The exposure device and source were returned to the company's storage area. The exposure device was surveyed and radiation levels were normal. The device and source were sent to the manufacturer for inspection. The manufacturer's inspection indicated that the ball connector on the source pigtail was bent. The exposure device was in good working order and was returned to service. The company replaced the source and provided additional training to personnel. The radiographer's 0 to 2 mSv (0 to 200 mrem) self-reading dosimeter went off scale during the event. His dosimeter was sent to out for processing. The company calculated the individual's exposure to be 4 mSv (400 mrem), based on an interview. They stated that no individual involved and no member of the general public received an exposure that exceeded any limit. The radiographer's processed badge revealed a reading of 3.12 mSv (312 mrem) DDE. The company's initial calculations for the exposure to the radiographer's hands revealed 4.5 mSv (450 mrem), which the Texas Department of State Health Services (TDSHS) questioned. Pictures of the radiographer's hands on 7/11/2018 showed no adverse effects from the exposure. The company contacted a service company to perform the dose calculations for the radiographer's hands. Their estimates revealed 11.8 cSv (rem) for a one-second exposure. The company provided a video showing the radiographer disconnecting the guide tube from the exposure device. The disconnection required less than one second. Therefore, the extremity exposure would be less than 12 cSv (rem).

Item Number 180265 - A high dose rate (HDR) afterloader unit malfunctioned during patient treatment. The HDR unit contained a 111 GBq (3 Ci) Ir-192 source. A patient was undergoing vaginal treatment on 6/5/2018 when the afterloader unit malfunctioned. The patient was prescribed to receive 1,500 cGy (rad) during three fractions. The treatment plan was to deliver the first fraction using 13 dwell points, but the afterloader failed at dwell point nine. The manufacturer was notified and repaired the afterloader. The written directive was modified for the second and third treatment fractions and the patient received their total prescribed dose. This event was classified as an EQP and MED event.

Item Number 180333 - A foundry reported that a piece of refractory brick inside a cupola broke loose on 6/28/2018, which caused a fixed nuclear gauge in the vicinity to become very hot, damaging the source shielding. The gauge contained an 18.5 GBq (500 mCi) Cs-137 source (assayed 1999). The gauge was taken out of service and placed into storage. A radioactive waste broker took possession of the gauge on 7/19/2018.

Item Number 180340 - A construction materials testing company reported that a moisture/density gauge containing a 1.63 GBq (44 mCi) Am-Be source and a 0.17 GBq (4.6 mCi) Cs-137 source was damaged. While performing measurements at a construction site in Big Rapids, Michigan, on 7/16/2018, the gauge user walked approximately 15 feet away from the gauge to retrieve a clipboard. At that time, a bulldozer struck the gauge while the source rod was extended. The gauge's plastic case and electronics panel were cracked and broken, the indexing rod was sheared, and the source rod was bent such that it could not be

retracted. The bent source rod also prevented the gauge from being placed into its transport case. The Am-Be source remained in its shielded position. The area around the damaged gauge was cordoned off. The RSO and an office technician travelled to the site. Radiation levels were 0.6 to 0.8 μSv/hr (0.06 to 0.08 mrem/hr) at three feet from the gauge, and 200 to 300 µSv/hr (20 to 30 mrem/hr) at one foot from the exposed Cs-137 source. Various attempts were made to retract the Cs-137 source into the shielded position, including manually bending the source rod (with bare hands approximately eight inches from the exposed source for up to two minutes) and striking the end of the source rod (where the source was located) with a hammer. On the second hammer strike, the welded cap on the end of the source rod shattered and the now singly encapsulated source fell out of the cup on the end of the source rod. The gauge user picked up the source with his bare hands, inspected the capsule for damage, and set it down, holding the source for no more than 10 seconds. A spool of copper wire was placed over the source to provide some shielding. A box was partially filled with sand and the gauge user moved the source by hand (holding it for no more than 10 seconds) into the box before filling the rest of the box with sand. The RSO sealed the box and placed it in the trunk of his car, along with the remnants of the gauge and its transport case. The source and gauge were secured in a storage shed that night at the company's office. Radiation levels were 4 µSv/hr (0.4 mrem/hr) at three feet from the box, and 2 µSv/hr (0.2 mrem/hr) at the same distance from the box while outside the shed. A gauge manufacturer provided leak test collection equipment, a lead pig, and instructions to remove the source rod so that the gauge would fit in its transport case. The leak test results were negative. The source and gauge were transported to a service center on 7/17/2018. The NRC estimated that the gauge user received 1.22 mVs (122 mrem) SDE to his hands, while the office technician received 0.02 mSv (2 mrem) to his hands. To prevent recurrence, nuclear gauge refresher training will be developed to reinforce the safety procedures and incident response. A lead-lined, 55-gallon transport vessel will be available for incidents where a damaged gauge cannot be placed into its transport case. Additional staff with RSO training and experience will be identified as part of an incident response team.

Item Number 180356 - A medical center reported that a patient may have received dose to an unintended site and less dose than prescribed to the intended site during a high dose rate (HDR) brachytherapy treatment on 7/17/2018. The procedure was performed with an HDR unit, a 190.92 GBq (5.16 Ci) Ir-192 source, and three applicators (for the tandem and left/right ovoids). After the first fraction, the radiation therapist noted that the distal end of the transfer guide tube for channel 1 (used for the tandem applicator) was hanging vertically along the end of the gurney. It appeared that the transfer tube for channel 1 had been severed at its distal end from its connector. A survey of the patient confirmed that the source had retracted into the HDR device. Initially, the medical center was unable to determine if the transfer guide tube failed before the source deployed to the treatment site or upon return of the source to the HDR unit. It is possible that the patient received the planned treatment. It is also possible that the source landed on the gurney close to the patient's skin, or that the source extended vertically down from the distal end of the transfer tube. Staff immediately notified the HDR manufacturer and removed the tubing from service. Staff also notified the patient's physician. The California Health and Human Services Agency performed a follow-up site visit on 7/20/2018. Based on continuous monitoring of the patient, both internally at the treatment site and also externally on the patient's skin, the radiation oncologist determined that the patient received their prescribed dose as intended. It appears that the guide tube failure occurred upon completion of the patient's treatment. Therefore, the source did not land on the gurney close to the patient's skin or extend vertically down from the distal end of the transfer tube. The prescribed and administered dose was 600 cGy (rad) per fraction, with a total dose of 3,000 cGy (rad) delivered over five fractions. Replacement guide tubes were purchased prior to any further patient treatments.

Item Number 180429 - A construction services company reported that a moisture/density gauge was run over by construction equipment at a temporary job site in Monterey Park, California, on 9/7/2018. The gauge contained a 1.85 GBq (50 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source. The damage resulted in the loss and recovery of the Cs-137 source. Following the accident, the gauge operator notified his RSO. He sent photographs of the broken gauge handle and said that the source rod

was bent. He retracted the source rod, secured the gauge inside the transport container, and transported the gauge to their permanent storage site. The RSO visually inspected the gauge on 9/9/2018 and instructed the gauge operator to transport it to a gauge service center on 9/10/2018. The service center discovered that the tip of the rod containing the Cs-137 source had broken off and was missing. The Am-Be source was in place. The RSO contacted the job site supervisor concerning the missing source and ensured that personnel were not working in the accident area. The gauge operator and RSO went to the accident site to search for the Cs-137 source. They located the source and used eight-inch long pliers to place it into shielding. The source was then transported to the gauge service center for evaluation and emergency leak testing. The California Health and Human Services Agency (CHHSA) investigated the incident. As part of their corrective actions, the construction services company purchased a radiation survey meter and will maintain annual calibrations, perform accident prevention actions, and provide emergency procedure training to all gauge operators. They also amended their emergency procedures such that the RSO will notify CHHSA immediately of an event involving significant damage to a gauge, and they will conform to regulatory reporting of gauges that have been damaged and could lead to radiation contamination or exposure. This event was classified as an EQP and MED event.

2.7.3 Events Recently Added to NMED That Occurred Prior to FY18

Six EQP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest

None

2.8 Transportation

2.8.1 Ten-Year Data

Figure 8 displays the annual number and trend of TRS events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

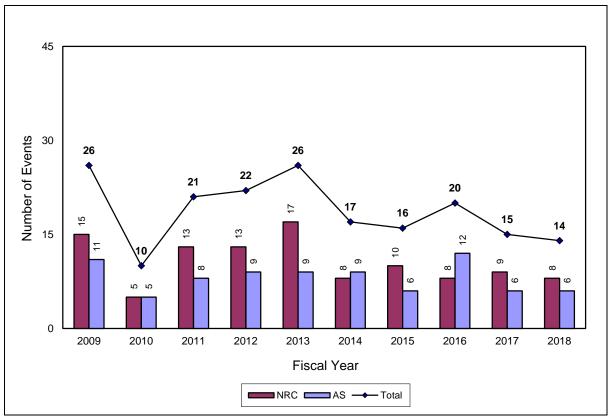


Figure 8. Transportation Events (187 total)

It is not possible to discern the significance of TRS events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.8.2 FY18 Data

Fourteen TRS events occurred in FY18, none of which were considered significant.

Significant Events

None

Events of Interest

Item Number 170492 - A medical center received a package on 10/23/2017 with external radiation levels from 190 to greater than 200 mR/hour on contact. The package contained approximately 12.58 GBq (340 mCi) of Tc-99m sent from a radiopharmacy. The incident was identified while performing daily equipment checks in the hot laboratory, about one hour following receipt. A wipe test of the package exterior was performed with negative results. The package was isolated behind lead bricks and the RSO and radiopharmacy were contacted. On 10/27/2017, following a period of decay, the package was

opened. A wipe test of the package interior was performed with negative results. It was discovered that the cover of the lead shield containing the vial of Tc-99m had separated from the bottom portion of the shielding, resulting is a 1.2 cm gap in the shielding (the two pieces were held together by shrink wrap applied at the radiopharmacy). The pharmacist had failed to properly secure the cover of the shielding container. The radiopharmacy implemented a policy in which all employees who handle shielding containers will challenge the covers to ensure that they are securely fastened prior to placement in the shipping packages.

2.8.3 Events Recently Added to NMED That Occurred Prior to FY18

Three TRS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events None

Events of Interest

None

2.9 Other

2.9.1 Ten-Year Data

Figure 10 displays the annual number of OTH events that occurred during the 10-year period. Because OTH events do not fit a defined criterion that ensures consistency within the data, trending analysis is not performed on this data.

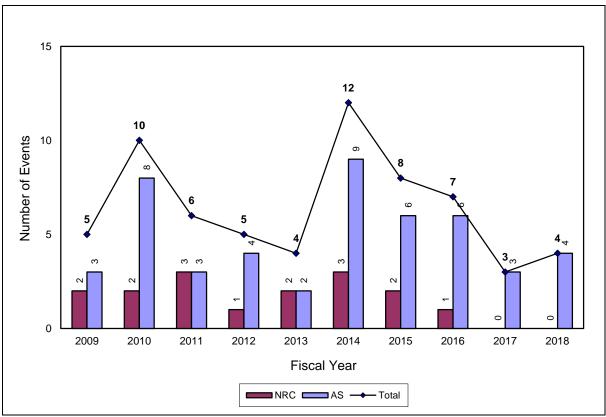


Figure 9. Other Events (64 total)

It is not possible to discern the significance of OTH events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.9.2 FY18 Data

Four OTH events occurred in FY18, none of which were considered significant.

Significant Events

None

Events of Interest

Item Number 170480 - The Texas Department of State Health Services (TDSHS) reported an alarm system breach that occurred in their exchange building on 10/10/2017. The security company called TDSHS stating that the alarm to the source room was triggered. The room contained many calibration sources. Two of the sources were part of calibration units. One high range calibration unit contained a 2,220 GBq (60 Ci) Cs-137 source and the other instrument calibrator contained a 0.24 GBq (6.56 mCi) Cs-137 source. Personnel responded to the room and checked the door, finding it locked. The alarm

system was turned off by entering a code. The security company was called and provided information to stop local law enforcement from responding. A postal service technician (who is not escort authorized) was next door and had been asked by contractors to open the source room door. She went to the building operations office, got the key, and opened the door for the contractors. She stated that when the alarm sounded, she closed the door and notified the security guard, who notified TDSHS. A TDSHS investigator stayed with the contractors and then reset the alarm when they were finished. An investigation of the event was performed. Corrective actions included the RSO retraining personnel on the importance of security and room access. The door was also re-keyed to prevent recurrence.

Item Number 180262 - An oil refinery reported an exposure rate greater than 0.02 mSv/hour (2 mrem/hour) in an unrestricted area. On 5/31/2018, during a turn-around job, lock-out and tag-out procedures were not performed on two fixed gauges. The gauges were mounted on a vacuum distillation tower and each contained a 1.85 GBq (50 mCi) Cs-137 source. Two non-radiation workers were exposed to the sources. Their radiation exposures were estimated at between 0.2 and 0.4 mSv (20 and 40 mrem) whole body. Corrective actions included modifying an equipment identification form to include the shutter status of each source and operations personnel sign-off prior to a work permit being issued for the tower. The radiation safety office will place locks on the gauges prior to operations personnel entering the confined space. "Radiation Hazard - Contact RSO Before Entry" signs will be installed on the tower manway. Training on this incident was included in the July safety meeting for all personnel.

2.9.3 Events Recently Added to NMED That Occurred Prior to FY18

No OTH events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest

None

Appendix A Event Type Descriptions and Criteria

Appendix A Event Type Descriptions and Criteria

The NMED events covered by this report are divided into the following categories based on the event reporting requirements defined in 10 CFR. Note that the tables in this appendix do not contain the full text of the applicable CFRs.

Lost/Abandoned/Stolen Material (LAS)

The LAS event category includes those events where licensed radioactive material is lost or found, abandoned or discovered, and stolen or recovered. The radioactive material involved can be sealed or unsealed material, specifically or generally licensed, exempt or non-exempt quantities, involve a licensee or a non-licensee, and can be found anywhere. Abandoned well logging sources are included in this category.

NMED LAS reportable events are those that meet the reporting requirements of 10 CFR Part 20.2201. Events that do not meet the 20.2201 reporting requirement thresholds are captured as not-reportable LAS events. Additionally, LAS events involving non-Atomic Energy Act material are entered into NMED as not-reportable events.

All reportable LAS events will be coded as one of the following reporting requirements. For events involving more than one source, the decision of $10 \times$ or $1,000 \times$ the 10 CFR Part 20 Appendix C quantity is based on the aggregate quantity of licensed material.

Table A-1. Primary LAS Reporting Requirements

Primary LAS Reporting Requirements	Reporting Requirement Summary
20.2201(a)(1)(i)	Aggregate activity ≥ 1,000 × 10 CFR Part 20 Appendix C quantity
20.2201(a)(1)(ii)	Aggregate activity > 10 and < 1,000 × 10 CFR Part 20 Appendix C quantity
39.77(d)	Irretrievable well logging source

The following additional (secondary) CFRs will be added as applicable. This should occur infrequently. For the 10 CFR 37 requirements, the event will instead be coded as OTH if there was no actual theft, sabotage, or diversion of Category 1 or 2 quantities of radioactive material.

Table A-2. Secondary LAS Reporting Requirements

Secondary LAS Reporting Requirements	Reporting Requirement Summary
30.55(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H 3 (not generally licensed).
37.57(a)	Unauthorized entry resulted in actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of material.
37.57(b)	Suspicious activity related to possible theft, sabotage, or diversion of a category 1 or category 2 quantity of material
37.81(a)	A shipment of category 1 quantities of material is lost or missing.
37.81(b)	A shipment of category 2 quantities of material is lost or missing.
37.81(c)	Actual er attempted theft or diversion (or related suspicious activities) of a shipment of category 1 quantities of material.
37.81(d)	Actual or attempted theft or diversion (or related suspicious activities) of a shipment of category 2 quantities of material.
37.81(e)	Recovery of any lost or missing shipment of category 1 quantities of material.
37.81(f)	Recovery of any lost or missing shipment of category 2 quantities of material.

39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
40.64(c)(1)	Theft/diversion of 15 lb (or 150 lb per year) of source material (uranium or thorium).
73.71(a)(1)	Lost shipment of any SNM.
73.App G(I)(a)(1)	Actual or attempted theft or unlawful diversion of SNM.
74.11(a)	Loss, theft or unlawful diversion (actual or attempted) of SNM or the unauthorized production of enriched uranium.
76.120(a)(2)	Loss, other than normal operating loss, of special nuclear material.
76.120(a)(3)	Actual or attempted theft or unlawful diversion of special nuclear material.
150.16(b)(1)	Actual or attempted theft or unlawful diversion of SNM.
150.17(c)(1)	Attempted theft or unlawful diversion of more than 6.8 kg (15 lb) of Uranium or Thorium at any one time or more than 68 kg (150 lb) in any one calendar year.
150.19(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H-3 (not generally licensed). Note: This requirement is just like 30.55(c), but applies to Agreement States and offshore waters.

Medical (MED)

MED events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-3. MED Reporting Requirements

MED Reporting Requirements	Reporting Requirement Summary
35.3045(a)(1)(i)	Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(1)(ii)	Total dosage delivered differs from prescribed by 20% or more or falls outside the prescribed range; and results in a dose that differs from prescribed by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(1)(iii)	Fractionated dose delivered that differs from the prescribed dose for a single fraction by 50% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(2)(i)	Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(2)(ii)	Administration of a radioactive drug containing byproduct material by the wrong route of administration that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(2)(iii)	Administration of a dose or dosage to the wrong individual or human research subject that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(2)(iv)	Administration of a dose or dosage delivered by the wrong mode of treatment that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(2)(v)	Leaking sealed source that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(3)	Dose to the skin, organ, or tissue, other than the treatment site, that exceeds the prescribed dose by 0.5 Sv (50 rem) and 50% or more (excluding permanently implanted seeds that migrated from the treatment site).
35.3045(b)	Event resulting from patient intervention in which the administration of byproduct material or radiation from byproduct material results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Events are not considered MED events if they involve:

- Only a linear accelerator,
- Doses administered in accordance with a written directive (even if the directive is in error), or
- Patient intervention, unless the event results in unintended permanent functional damage to an organ or physiological system.

Events are considered MED events if, for example, a linear accelerator is used for therapy by mistake instead of a teletherapy unit or a teletherapy unit instead of a linear accelerator.

For purposes of determining whether to categorize an event as MED or EXP, MED events occur to patients only (i.e., those being administered a medical procedure). For example, if a patient receives too much dose during a procedure, the event would be categorized as MED rather than EXP. However, radiation exposure received from a cause other than the patient's medical procedure may be categorized as EXP.

Radiation Overexposure (EXP)

EXP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-4. EXP Reporting Requirements

EXP Reporting Requirements	Reporting Requirement Summary
20.2202(a)(1)(i)	An individual received a total effective dose equivalent of 25 rem (0.25 Sv) or more.
20.2202(a)(1)(ii)	An individual received a lens dose equivalent of 75 rem (0.75 Sv) or more.
20.2202(a)(1)(iii)	An individual received a shallow-dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more.
20.2202(b)(1)(i)	Loss of control of material causing or threatening to cause an individual to receive a total effective dose equivalent exceeding 5 rem (0.05 Sv) in a period of 24 hours.
20.2202(b)(1)(ii)	Loss of control of material causing or threatening to cause an individual to receive an eye dose equivalent exceeding 15 rem (0.15 Sv) in a period of 24 hours.
20.2202(b)(1)(iii)	Loss of control of material causing or threatening to cause an individual to receive a shallow-dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv) in a period of 24 hours.
20.2203(a)(2)(i)	Doses in excess of the occupational dose limits for adults in 20.1201.
20.2203(a)(2)(ii)	Doses in excess of the occupational dose limits for a minor in 20.1207.
20.2203(a)(2)(iii)	Doses in excess of the limits for an embryo/fetus of a declared pregnant woman in 20.1208.
20.2203(a)(2)(iv)	Doses in excess of the limits for an individual member of the public in 20.1301.
20.2203(a)(2)(v)	Doses in excess of any applicable limit in the license.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

The EXP event category includes all regulatory overexposures of radiation workers or exposures of members of the public to radiation. The overexposure can be external or internal and can be whole body, extremity, skin, lens of the eye, or internal dose. When the overexposure involves multiple individuals or an individual with multiple overexposure types (such as whole body and extremity), the different types of overexposures are entered separately. Note that dosimeters record exposure if improperly stored near a radiation source and, depending on the type of dosimeter, may react as though they are in a radiation field when exposed to heat or humidity.

It is NRC policy to classify only those events that positively involve a personnel overexposure, and not just a dosimeter exposure, as reportable EXP events. For example, either the licensee does not contest the personnel overexposure, or in cases where the licensee does contest the overexposure, the State or NRC determines the event to be personnel overexposure.

EXP limits do not apply to patients receiving medical procedures.

Release of Licensed Material or Contamination (RLM)

RLM events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-5. RLM Reporting Requirements

RLM Reporting Requirements	Reporting Requirement Summary
20.2202(a)(2)	Release of radioactive material, inside or outside of a restricted area, so that had an individual been present for 24 hours, the individual could have received an intake 5 times the ALI.
20.2202(b)(2)	Release of material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of 1 ALI.
20.2203(a)(2)(vi)	Doses in excess of the ALARA constraints for air emissions established under 20.1101(d).
20.2203(a)(3)(i)	Radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the license.
20.2203(a)(3)(ii)	Radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times any applicable limit set forth in Part 20 or in the license.
20.2203(a)(4)	Levels of radiation or releases of radioactive material in excess of the standards in 40 CFR Part 190, or of license conditions related to those standards.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(1) 40.60(b)(1) 70.50(b)(1) 76.120(c)(1)	Unplanned contamination event that requires access to be restricted for > 24 hours, involves > 5 times the lowest ALI, and has access restricted for a reason other than to allow isotopes with a half-life of < 24 hours to decay.
30.50(b)(3) 40.60(b)(3) 70.50(b)(3) 76.120(c)(3)	Event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
50.72(b)(3)(xii) 72.75(c)(3)	Event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

The RLM event category includes two types of events. The first type is a radioactive release to air or water exceeding the 10 CFR Part 20 Appendix B annual limit on intake (ALI). The second type of RLM event involves contamination events such as a radioactive spill outside of work areas, removable contamination found on equipment, or material tracked around a laboratory such that additional radiological control measures had to be implemented. This category does not include spills inside of laboratory hoods, radiopharmaceutical dose preparation areas, or hot cells where radioactive work routinely requires cleanup or changing of absorbent paper after the performance of a task. Should there be multiple release types (e.g., surface, air, water, or person) or areas of contamination associated with the release, this information is entered individually.

Leaking Sealed Source (LKS)

LKS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-6. LKS Reporting Requirements

LKS Reporting Requirements	Type of Source
31.5(c)(5)	Generally licensed
34.27(d)	Radiography
35.67(e)	Medical
39.35(d)(1)	Well logging (leaking)
39.77(a)	Well logging (ruptured)
30.50(b)(2)	All other sources

The NRC requires that most sealed sources be periodically leak tested to verify that the material is still sealed and that the source is still considered safe to use without contamination controls, including protective clothing or gloves. Sources are generally exempt from leak testing under the following conditions [see 10 CFR Part 31.5(c)(2), 34.27(c), 35.67(f), and 39.35(e)]:

- Sources containing only gaseous radioactive material (like H-3, Kr-85, etc.),
- Sources containing licensed material with a half-life of 30 days or less,
- Sources containing \leq 100 μ Ci of other beta and/or gamma emitting material,
- Sources containing $\leq 10 \mu \text{Ci}$ of alpha emitting material,
- Sources held in storage in the original shipping container prior to initial installation,
- Seeds of Ir-192 encased in nylon ribbon, or
- Sources in storage and not in use (must be leak tested prior to use or transfer).

A source is considered leaking if a leak test can detect greater than $0.005~\mu Ci$ of removable radioactive material. The leaking source is then removed from service, disposed of or returned to the manufacturer for repair, and a report is sent to the NRC or Agreement State with the details of the leaking source.

For regulatory reporting purposes, a leaking source is generally considered a failed device under 10 CFR Part 30. Therefore, in most cases an LKS event is also coded as an EQP event. An exception is the Ni-63 foil source, which is coded as only an LKS event.

Equipment (EQP)

EQP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-7. EQP Reporting Requirements

EQP Reporting Requirements	Reporting Requirement Summary
21.21(d)(1)(i)	A failure to comply or a defect affecting the construction or operation of a facility or an activity that is subject to licensing requirements.
21.21(d)(1)(ii)	A failure to comply or a defect affecting a basic component that is supplied for a facility or an activity that is subject to licensing requirements.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(2) 40.60(b)(2) 70.50(b)(2) 72.75(d)(1) 76.120(c)(2)	Equipment is disabled or fails to function as designed.
30.50(b)(4) 40.60(b)(4) 70.50(b)(4) 76.120(c)(4)	Unplanned fire or explosion that damages any licensed material or any device, container, or equipment containing licensed material.
31.5(c)(5)	Actual or indicated failure to shielding, the on-off mechanism or indicator, or upon the detection 0.005 uCi or more of removable radioactive material.
34.101(a)(1)	Unintentional disconnection of the radiographic source assembly from the control cable.
34.101(a)(2)	Inability to retract and secure the radiographic source assembly to its fully shielded position.
34.101(a)(3)	Failure of any radiographic component (critical to the safe operation of the device) to properly perform its intended function.
36.83(a)(1)	An irradiator source stuck in an unshielded position.
36.83(a)(2)	Fire or explosion in an irradiator radiation room.
36.83(a)(3)	Damage to the irradiator source racks.
36.83(a)(4)	Failure of the irradiator cable or drive mechanism used to move the source racks.
36.83(a)(5)	Inoperability of the irradiator access control system.
36.83(a)(6)	Detection of irradiator source by the product exit monitor.
36.83(a)(7)	Detection of irradiator radioactive contamination attributable to licensed radioactive material.
36.83(a)(8)	Structural damage to the irradiator pool liner or walls.
36.83(a)(9)	Abnormal water loss or leakage from the irradiator source storage pool.
36.83(a)(10)	Irradiator pool water conductivity exceeding 100 microsiemens per centimeter.
39.77(a)	Ruptured well logging sealed source.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
72.75(c)(1)	Defect in any spent fuel, HLW, or reactor-related GTCC waste storage structure, system, or component that is important to safety.
72.75(c)(2)	Significant reduction in the effectiveness of any spent fuel, HLW, or reactor-related GTCC waste storage confinement system during use.

72.242(d)	Design or fabrication deficiency for any spent fuel storage cask delivered to a licensee which affects the ability of components important to safety to perform their safety function.
	Salety function.

The EQP event category includes all types of radiological equipment problems, including generally licensed device problems covered in 10 CFR Part 31; radiography equipment problems covered in 10 CFR Part 34; irradiator problems covered in 10 CFR Part 36; well logging problems covered in 10 CFR Part 39, and other types of equipment covered in 10 CFR Part 30, 40, 70, and 76. EQP events are defined as the failure of, or a defect in, any piece of equipment that either contains licensed radioactive materials as an integral part, or whose function is to interact with such materials.

Transportation (TRS)

TRS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-8. TRS Reporting Requirements

TRS Reporting Requirements	Reporting Requirement Summary
20.1906(d)(1)	Transported package exceeds removable surface contamination limits.
20.1906(d)(2)	Transported package exceeds external radiation limits.
71.5	Transportation of licensed material.
71.95(a)(1)	Significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use.
71.95(a)(2)	Defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.
71.95(a)(3)	Conditions of approval in the Certificate of Compliance were not observed in making a shipment.
71.95(b)	Conditions in the Certificate of Compliance were not followed during a shipment.

Other (OTH)

The OTH event category includes the following types of events:

- 1. Doses to an embryo/fetus or nursing child reportable per 10 CFR Part 35.3047. Note that these events are not MED events (reportable per 10 CFR Part 35.3045).
- 2. Dose in an unrestricted area in excess of 2 mrem in an hour, but no individual received a dose in excess of limits (if a dose in excess of limits is received, the event is an EXP event).
- 3. 10 CFR 37 events that do not result in the actual theft, sabotage, or diversion of Category 1 or 2 quantities of radioactive material. Otherwise, the event is as an LAS event.
- 4. Reportable events that do not specifically fit into one of the previous event types.

For items 1-3 above, OTH events are determined and coded per the 10 CFR reporting requirements listed below. Due to the nature of item 4 above, other reporting requirements may also be used.

Table A-9. OTH Reporting Requirements

OTH Reporting Requirements	Reporting Requirement Summary
20.2203(a)(2)(iv)	Dose in an unrestricted area in excess of 2 mrem in an hour, but no dose received in excess of limits.
35.3047(a)	Dose to an embryo/fetus greater than 50 mSv (5 rem) DE from administration of byproduct material or radiation from byproduct material to a pregnant individual unless specifically approved, in advance, by the authorized user.
35.3047(b)(1)	Dose to a nursing child greater than 50 mSv (5 rem) TEDE resulting from an administration of byproduct material to a breast-feeding individual.
35.3047(b)(2)	Dose to a nursing child resulting in unintended permanent functional damage to an organ or physiological system, as determined by a physician, resulting from an administration of byproduct material to a breast-feeding individual.
37.57(a)	Unauthorized entry resulted in actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of material.
37.57(b)	Suspicious activity related to possible theft, sabotage, or diversion of a category 1 or category 2 quantity of material
37.81(c)	Actual or attempted theft or diversion (or related suspicious activities) of a shipment of category 1 quantities of material.
37.81(d)	Actual or attempted theft or diversion (or related suspicious activities) of a shipment of category 2 quantities of material.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

Appendix B Statistical Trending Methodology

Appendix B Statistical Trending Methodology

General

The following is a general discussion of statistical trending techniques.

A common approach to the statistical analysis of trend is based on regression methods. In particular, it is often the case that a relationship exists between the values assumed by a pair of variables. For example, if x is time (in years), and y is the rate of events per year, then we could use regression methods to study whether there is a relationship between time and event rate.

Regardless of the application, it is standard practice to refer to x as the independent variable and y as the dependent variable. Another common term for the dependent variable is "response variable," and the terms covariant and explanatory variable are sometimes used for the independent variable. Also, it is typical with regression modeling that the independent variable can be measured with little or no error, but the dependent variable involves a random error. Consequently, even if there is a deterministic functional relationship between the two variables, when data pairs (x_1, y_1) , (x_2, y_2) ,..., (x_n, y_n) are plotted, the points will not coincide exactly with the function, but instead will tend to be scattered. Such a plot is called a scatter diagram, and shows the variation in the data. The plots in this report are bar charts containing the same information.

Fitting a Straight Line to Data

Consider a linear function

$$f(x) = \alpha + \beta x \tag{B-1}$$

where α and β are unknown parameters. A common model is that y is the sum of a linear function of the form (1) and a random error term, e. Standard results on estimation and inference about the parameters of the model assume that e is a normally distributed random variable with mean 0 and constant (but unknown) variance, σ^2 . These assumptions mean that:

- Each yi is an observed value of a random quantity that is normally distributed [with mean f(xi)], and
- All the observations yi are of variables with a common variance, σ^2 .

The y_i are also assumed to be observations of random quantities that are independent of each other.

Under these conditions, the usual approach to estimating the unknown parameters α and β is the method of least squares (LS). In this method, α and β are selected so that the sum of the squares of the vertical distances between the data points and the fitted line is as small as possible. The LS method leads to the estimates

$$\hat{\beta} = \frac{\sum_{i=1}^{n} (x_i - \bar{x}) y_i}{\sum_{i=1}^{n} (x_i - \bar{x})^2} \text{ and}$$
(B-2)

$$\hat{\alpha} = \overline{y} - \hat{\beta}\overline{x} \,, \tag{B-3}$$

where \bar{x} and \bar{y} are arithmetic averages. The estimated LS regression line is then

$$\hat{y} = \hat{\alpha} - \hat{\beta}x, \tag{B-4}$$

and an estimate of σ is

$$s = \sqrt{\frac{\sum_{i=1}^{n} (y_i - \hat{y}_i)^2}{n - 2}} . \tag{B-5}$$

Testing for Trend

A trend exists whenever the true slope, β , is not zero. We start the analysis with the idea that β is zero, and then ask whether the data tell us otherwise. Two quantities computed from the data are used in this assessment. The first, the *error sum of squares* (SSE), appears in the numerator of s. It is defined as

$$SSE = \sum_{i=1}^{n} (y_i - \hat{y}_i)^2.$$
 (B-6)

This quantity is the number that is minimized in order to find the estimates of α and β . The differences being squared in SSE represent random variations that remain after the linear fitting process. The second quantity is the *regression sum of squares* (SSR), defined by the following equation

$$SSR = \sum_{i=1}^{n} (\hat{y}_i - \bar{y})^2. \tag{B-7}$$

Note that SSR looks at deviations between the fitted line and the default notion that the data are constant and have no slope.

One can show by algebra that

$$SSE + SSR = SST, (B-8)$$

where the total sum of the squares (SST), is defined as

$$SST = \sum_{i=1}^{n} (y_i - \overline{y})^2. \tag{B-9}$$

SST measures the overall variation in the data. It is the numerator that would be used to estimate the variance in a sample from a normally-distributed random variable, where all the data in the sample have the same distribution (and thus no trend). This variance measures "random variation" in such a sample.

In the framework of the linear function (1), the regression's effectiveness is measured by the *SSR* term defined above. When it is small, the fitted curve will not differ very much from the horizontal line $y = \overline{y}$. *SSE* will be approximately equal to *SST*, and, from the data, both *SSE* and *SST* will be estimates of mere random variation. In this case, the data does not provide evidence that β is different from zero.

On the other hand, if the y values tend to vary linearly with respect to the independent variable, x, then some of the variation in the y values can be attributed to this dependence on x. Since SSR assesses the difference between the least squares predictions of the y values and the arithmetic mean, \bar{y} , it is a measure of the variation which is "explained" by the linear relationship. When the slope of the fitted line is large, more of these differences will tend to be large, resulting in a large value of SSR.

In the equation, SST = SSE + SSR, the total variation is partitioned into two parts, the variation due to random error and the variation due to the linear relationship. The fraction of the total variation that is due to the linear relationship is called the coefficient of determination, or r^2 , and is defined by:

$$r^2 = \frac{SSR}{SST} \,. \tag{B-10}$$

 r^2 is a fraction that varies from 0 to 1. It will be near 0 if most of the variation is due to randomness, and it will be near 1 if most of the variation is due to the linear relationship.

The closeness to 1 needed for the data to show that the slope is not zero depends on the number of data points. If the dependent data are independent, normally-distributed at each x, with constant variance, and no trend, then the quantity, F, defined by

$$F = \frac{(n-2)r^2}{1-r^2}$$
 (B-11)

can be shown to have an F distribution with degrees of freedom 1 and n-2, where n is the number of data points. When the data satisfy the assumptions except that there is a significant trend, r^2 will be closer to 1 and the computed F statistic will be much larger. Specifically, if the computed F exceeds the upper fifth percentile of the F distribution with 1 and n-2 degrees of freedom, we infer that the data contain evidence that β is not zero, at the 5% level of significance. In this case, we reject the null hypothesis that $\beta = 0$ and conclude that a statistically significant trend exists, with 95% confidence.

As an example, for an assumed set of data fit to the linear model, assume the $r^2 = 0.9369$ and that n is 13. Then the calculated F is 163.3. The upper 95th percentile of the F(1,11) distribution is 4.84. Since 163.3 far exceeds the upper 95th F percentile, the linear model is statistically significant. In this example, the data show that it would be very unlikely for a trend not to exist. The linear model explains too much of the variation in the data for a trend not to exist.

Applying the Model to the NMED Data

The method described above was applied for each category of NMED event data, for the overall NMED data, and for additional subgroups of data when trends were found in the overall data. When the calculated F exceeded the 95th percentile, the trend line was shown on the graph and identified as being statistically significant.

In future reports, methods slightly different than that explained above could be employed because the NMED data in many cases does not follow the assumptions listed above. In particular, three considerations apply.

- The data are counts, and thus are discrete rather than being normally distributed. This problem is most pronounced when the counts are relatively low or sparse. Also, normally-distributed data in general can be negative, but the counts are always greater than or equal to zero.
- Variations in counts tend to increase as the counts increase. If the events occur at random, with a constant occurrence rate in a particular year or quarter, then the variance of the count for that year or quarter is equal to the mean or average for that year or quarter. Thus, the assumption of a constant variance for the data in each year may not apply.
- Finally, more than one count can be associated with a single reported incident in a single event category. This situation would occur, for example, if several pieces of equipment fail in an event or if several types of overexposure occur. In these cases, the data are not independent.

One way to address the first two concerns is to identify the number of licensees in various NMED categories and study the event occurrence rates rather than the counts. The rates are more likely to come from a continuum, and might have a more constant variance.

Taking logarithms of the counts and then applying the LS method avoids the problem of possible negative trend lines. The resulting models can be converted back to the scale of the counts after the regression line is identified. In the scale of the counts, the resulting trend, if any, has a slight curvature.

Weighted regression is a method similar to the LS method described above, but it compensates explicitly for the effect of the different variances from year to year.

Another approach that deals with the first two concerns is to apply regression methods that have been designed specifically for counts. Poisson regression, for example, is based on the idea that the data in each time period are counts observed from a Poisson distribution, with an occurrence rate that is described by the model. Given occurrence rates in each time period, and independent counts, the probability of seeing the observed data is easily computed by multiplying the occurrence probabilities for the individual time periods. The slope and intercept parameter estimates are selected so that the model maximizes the resulting "likelihood function."

The third issue may have little effect on the results of a trend analysis, as long as there are many counts with relatively few occurring in clumps, no trends in the occurrence of clumps, and no large clumps of counts coming from a single occurrence report. The best way to address the dependence issue is to identify and remove the duplicate counts prior to the trend analysis.

Appendix C IAEA Radionuclide Categorization

Appendix C IAEA Radionuclide Categorization

Table C-1 lists the radionuclides that this report uses to determine the significance for events involving the loss, abandonment, or theft of radioactive sources. This list is derived from the IAEA *Code of Conduct on the Safety and Security of Radioactive Sources (2004)* and from IAEA Safety Guide RS-G-1.9, *Categorization of Radioactive Sources*. Based on the amount of radioactivity involved, the radionuclides are grouped into five categories, with Category 1 being the most hazardous. These categories may be summarized as follows (derived from IAEA Safety Guide RS-G-1.9, *Categorization of Radioactive Sources*):

- **Category 1: Extremely dangerous.** These sources could cause permanent injury within a few minutes if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from a few minutes to an hour.
- **Category 2: Very dangerous.** These sources could cause permanent injury within minutes to hours if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from hours to days.
- **Category 3:** Dangerous. These sources could cause permanent injury within hours if handled. Doses could possibly (but unlikely) be fatal to someone in close proximity to an unshielded source for periods ranging from days to weeks.
- **Category 4: Unlikely to be dangerous.** These sources would not cause permanent injury, although delayed health effects are possible. Doses could possibly (but unlikely) cause temporary injury to someone in close proximity to an unshielded source for a period of many weeks.
- **Category 5:** Most unlikely to be dangerous. These sources would not cause permanent injury.

C⁷

Table C-1. IAEA Code of Conduct Category 1 through 5 Radionuclide Activity Thresholds

	Category 1		Category 2		Category 3		Category 4		Category 5	
Radionuclide	TBq	Ci ¹								
Am-241	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Am-241/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Cf-252	20	541	0.2	5.4	0.02	0.54	0.0002	0.0054	1.0e-08	2.7e-07
Cm-244	50	1,352	0.5	13.5	0.05	1.35	0.0005	0.0135	1.0e-08	2.7e-07
Co-60	30	811	0.3	8.1	0.03	0.81	0.0003	0.0081	1.0e-07	2.7e-06
Cs-137	100	2,703	1.0	27.0	0.10	2.70	0.001	0.0270	1.0e-08	2.7e-07
Gd-153	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-05	2.7e-04
Ir-192	80	2,162	0.8	21.6	0.08	2.16	0.0008	0.0216	1.0e-08	2.7e-07
Pm-147	40,000	1,081,200	400.0	10,812.0	40.00	1,081.20	0.4	10.8120	1.0e-05	2.7e-04
Pu-238	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Pu-239/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Ra-226	40	1,081	0.4	10.8	0.04	1.08	0.0004	0.0108	1.0e-08	2.7e-07
Se-75	200	5,406	2.0	54.1	0.20	5.41	0.002	0.0541	1.0e-06	2.7e-05
Sr-90 (Y-90)	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-08	2.7e-07
Tm-170	20,000	540,600	200.0	5,406.0	20.00	540.60	0.2	5.4060	1.0e-06	2.7e-05
Yb-169	300	8,109	3.0	81.1	0.30	8.11	0.003	0.0811	1.0e-05	2.7e-04

Notes

1. The primary values are given in TeraBequerel (TBq). Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.

Appendix D Revision of Data

Appendix D Revision of Data

The NMED is a dynamic database with new reports and revisions to previous reports being added on a continuing basis. This activity can result in additions or subtractions to data that was published in previous issues of this report. Numerical changes in NMED numbers can result from several different types of technical changes to coded data. The most common types of changes to database records are:

- Record additions due to late reporting
- Record additions or subtractions due to changes in event type
- Changes between fiscal years due to event date changes on individual events
- Record additions or subtractions due to changes in event reportability
- Record additions or subtractions due to reclassifying a single combined event as multiple individual events (or vice versa)
- Record deletions due to duplicated records or NRC direction

Figures D-1 through D-9 below display the changes in the data published in the previous annual report. A positive value indicates that records were added and a negative value indicates that records were removed.

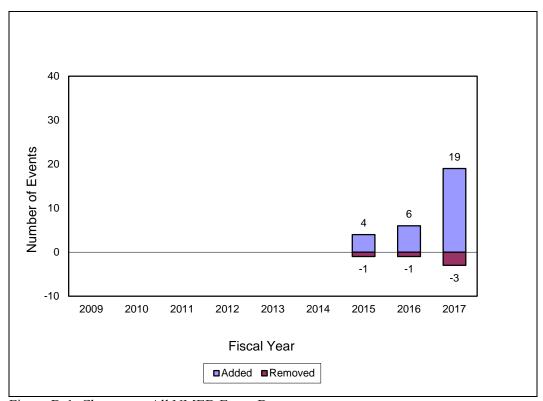


Figure D-1. Changes to All NMED Event Data

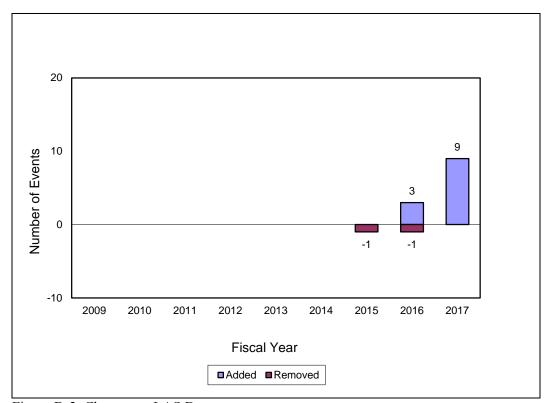


Figure D-2. Changes to LAS Data

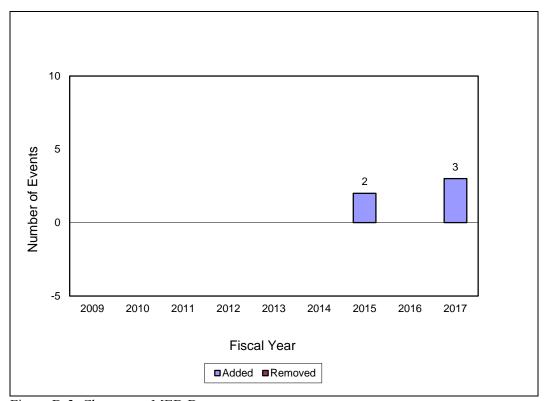


Figure D-3. Changes to MED Data

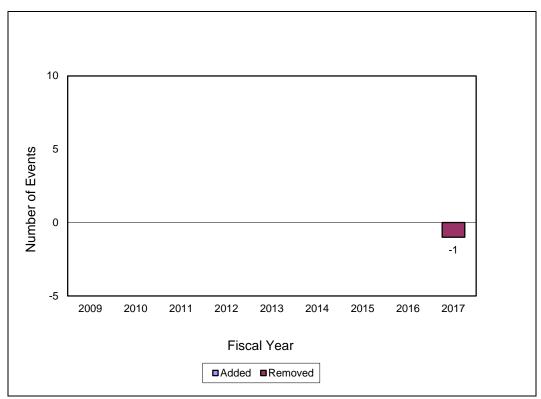


Figure D-4. Changes to EXP Data

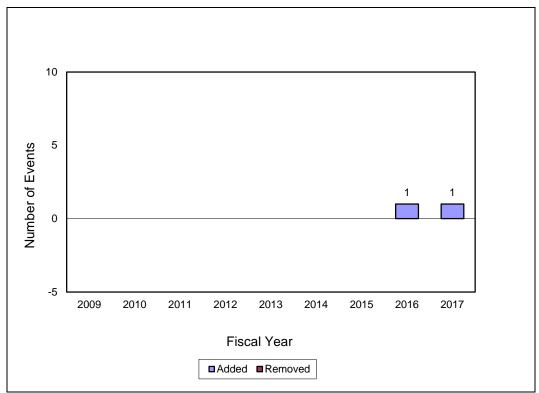


Figure D-5. Changes to RLM Data

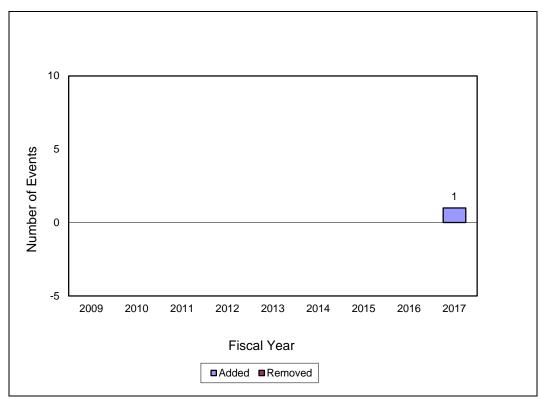


Figure D-6. Changes to LKS Data

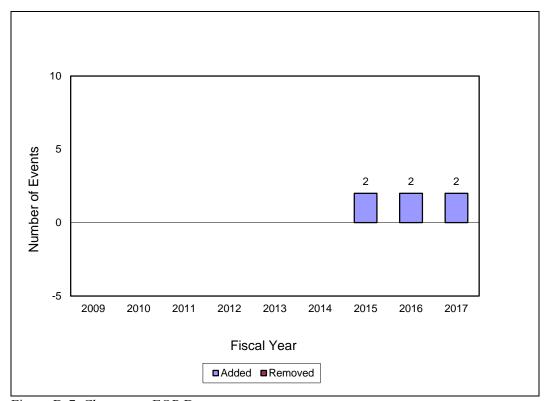


Figure D-7. Changes to EQP Data

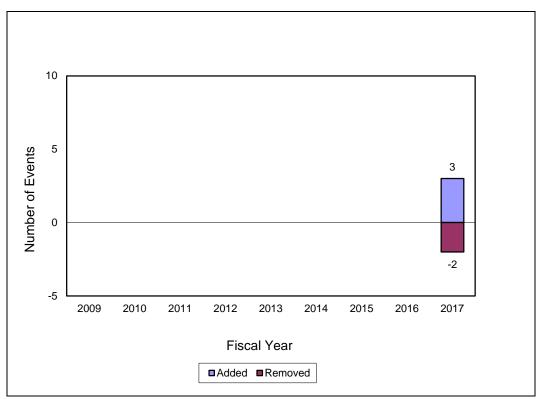


Figure D-8. Changes to TRS Data



Figure D-9. Changes to OTH Data